US & Multilateral Trade and Policy Developments

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Contents

Trade Policy Developments

United States Preparing New Import Rules for Product Safety Certifications

The US Consumer Product Safety Commission (CPSC) is preparing to issue a final rule amending the consumer products safety compliance certification system for importers. Crucially, the updated rules will implement a new requirement that importers of CPSC-regulated consumer products must electronically file certificates of regulatory compliance through US Customs and Border Protection's (CBP) Automated Commercial Environment (ACE) Partner Government Agency (PGA) Message Set alongside their customs declarations. CPSC began a voluntary phase of this "eFiling" process in summer 2024, allowing importers to begin adopting and testing the system before its entry into force.[1] According to CPSC, issuance of the final rule is scheduled for around the end of 2024, with the full implementation of the eFiling system to occur in 2025.

The CPSC originally issued the notice of proposed rulemaking in 2013 but decided not to move forward with the proposal at that time due to widespread stakeholder objections. Since 2013, the CPSC has made several modifications to the proposed rule and run pilot tests of the electronic filing system with CBP. The CPSC revived the rulemaking process in December 2023, issuing a supplemental notice of proposed rulemaking (SNPRM).[2] The Biden administration highlighted the CPSC's plans in a September 13, 2024 announcement on *de minimis* entry reform efforts.[3] The White House statement described the CPSC rule as part of a broader government strategy to "enforce our laws and protect American consumers, workers, and businesses by addressing the significant increased abuse of the *de minimis* exemption, in particular China-founded e-commerce platforms, and strengthening efforts to target and block shipments that violate U.S. laws."

Development of the new requirements

The 2008 Consumer Product Safety Improvement Act (CPSIA) introduced the current certificate of compliance requirements, which are established in 16 CFR part 1110 (the "1110 rule").[4] The CPSIA amended the Consumer Product Safety Act (CPSA) to require that manufacturers and importers issue certificates for all consumer products subject to a consumer product safety rule under the CPSA. The 1110 rule amendments the CPSC issued in 2008 to implement the CPSIA's new requirements were intended to be temporary, adopting an approach that was "streamlined, at least in its initial phase."[5] The CPSC stated then that it would consider further revisions as certifications become more routine. However, the 2008 updates remain the prevailing regulations today.

The 1110 rule requires that the relevant certificates of compliance "be available to the Commission from the importer as soon as the product or shipment itself is available for inspection in the United States." Importers and domestic manufacturers are expected provide reasonable means to access certificates of compliance to distributers and retailers. There are no mandatory filing processes. For importers, the CPSC requests access to the applicable certification after stopping an import shipment for inspection. The CPSC believes this import process is labor intensive and lacks sufficient data for adequate risk-based targeting of suspicious shipments.

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[1] Information on the eFiling system can be found on the CPSC website, accessible here: https://www.cpsc.gov/eFiling.

[2] "Certificates of Compliance," 88 FR 85760 (December 8, 2023), accessible here: https://www.federalregister.gov/documents/2023/12/08/2023-25911/certificates-of-compliance. More information on the eFiling process and rules is available in the CPSC staff briefing package, accessible here: https://www.cpsc.gov/s3fs-public/Ballot-Package-Draft-SNPR-to-Revise-16-CFR-part-1110-Certificates-of-Compliance.pdf?VersionId=3DjqxMqgXJNQ0yeFRgKzfsRj2GgKenqD.

[3] "Biden- Harris Administration Announces New Actions to Protect American Consumers, Workers, and Businesses by Cracking Down on De Minimis Shipments with Unsafe, Unfairly Traded Products," White House, September 13, 2024, accessible here: https://www.whitehouse.gov/briefing-room/statements-releases/2024/09/13/fact-sheet-biden-harris-administration-announces-new-actions-to-protect-american-consumers-workers-and-businesses-by-cracking-down-on-de-minimis-shipments-with-unsafe-unfairly-traded-products/.

[4] 16 CFR Part 1110, accessible here: https://www.ecfr.gov/current/title-16/part-1110.

[5] "Certificates of Compliance," 73 FR 68328 (November 18, 2008), accessible here: https://www.federalregister.gov/documents/2008/11/18/E8-27356/certificates-of-compliance.

In 2013, the CPSC proposed to further amend the 1110 rule to (i) align it with children's products testing rules under 16 CFR part 1107 (the "1107 rule") and the product component part testing rules under 16 CFR part 1109 (the "1109 rule") (which the CPSC had developed after issuing the 2008 updates to the 1110 rule) and (ii) to require eFiling of certificates of compliance for imported consumer products at the time of entry. Developing the eFiling proposal was motivated by needs to refine risk assessments and address the rise of direct-to-consumer cross-border e-commerce, which the CPSC noted was making the interdiction of noncompliant products harder. However, the proposal quickly encountered challenges. CBP had not yet completed the development of ACE or the PGA Message Set. Without the completed CBP systems in place, importers argued the eFiling requirement was infeasible. After gathering public feedback on the proposal, CPSC decided that introducing the eFiling system would have been premature.

Since 2013, CBP has implemented ACE and developed the PGA Message Set, allowing the CPSC to revive the 2013 proposed rule. The CPSC Commission approved a new multi-year plan to implement the full eFiling system in December 2020, which lead to the issuance of the SNPRM and the initiation of a beta pilot test. The SNPRM makes various technical changes to the original proposed rule, though the general scope and core requirements remain the same. Among the changes, the CPSC expanded its definition of importer, reverted to the 1110 rule's original language on who must certify products, added more detail on required data elements, added a requirement for importer attestation certifying compliance, declined to add requirements that the importer disclose the date of initial certification and the scope of the finished product(s) covered by the certificate, and updated certain sections based on the completion of the ACE filing systems.

Covered products

The requirements apply to all imported finished consumer products and other substances that the CPSC regulates. Among the covered products are toys, magnets, products containing button-cell batteries, various articles of furniture, bicycles, and some home construction materials. Replacement parts for regulated products "imported for consumption or warehousing or are distributed in commerce that are packaged, sold, or held for sale to, or use by, consumers" are considered finished products. Unfinished components intended for use in the manufacturing of a finished product by a domestic manufacturer would generally not be subject to the eFiling requirement.

The United States imported US$247.92 billion worth of products under HTS codes regulated by the CPSC in 2023,[6] $5.4 billion of which originated in Japan (3.7% of total US goods imports from Japan). The United States imported products from Japan under 1,095 covered HTS codes, with the most imports in categories such as electric vehicles, pharmaceuticals, video game consoles, garage door openers, and beauty and skin care products.

The proposed eFiling system

The CPSC proposes to require importers to eFile their certificates of compliance with CBP, either when the entry is filed or when the entry and entry summary are filed (if they are filed together), for all imported finished products subject to a CPSC regulation. *De minimis* shipments and products imported from a US Foreign Trade Zone (FTZ) are included in the requirement. The CPSC is providing several methods for eFiling, summarized below:

- **eFiling with the Reference PGA Message Set:** Importers would pre-register their certificates of compliance through the CPSC's Product Registry, a CPSC-maintained database in which importers can store certificates. The Product Registry will generate unique identifiers for the importer's certificates (a Certifier ID, Product ID, and Version ID), which the importer would then relay to their customs broker. The customs broker would enter the Product Registry's identifiers in ACE's Reference PGA Message Set. The CPSC believes this streamlined system will be preferable for most importers (especially those that repeatedly import the same types of products under the same certificates of compliance) because the importers will not have to enter full certification data for every shipment.

[6] Data from US Census Bureau via USA Trade Online, accessed October 7, 2024. Totals are based on HTS codes provided in the CPSC Staff's SNPR Briefing Package. In some cases, not all products under a given HTS-10 code may be subject to the regulations.

- **eFiling with the Full PGA Message Set:** When using the CPSC Product Registry is impractical, importers and their brokers would have to file the more detailed Full PGA Message Set. The importer would compile all certificate data and work with their brokers to file all the data in ACE. The CPSC recommends this approach for importers that are importing a limited number of regulated consumer products or that do not repeatedly import the same product.
- **Postal entry:** For postal shipments, all data would have to be directly entered into the CPSC Product Registry before the postal shipment arrives in the United States. For this purpose, the US Postal Service itself would not be considered the importer. Instead, the SNPRM's proposed definition of importer would allow either the US-based entity receiving the shipment or the foreign entity that sent the shipment to be importer for the eFiling.

An importer completing the eFiling (either in advance through the Product Registry or directly through the Full PGA Message Set) would provide the seven data elements that are specified in the 1110 rule. The required disclosures cover identification of the imported item; citation codes for all applicable CPSC-enforced standards; date and place of the most recent conformity tests; point of contact for the party maintaining the test results; date and place of final manufacture; and contact information of the final manufacturer. The importer would also have to complete an attestation certifying the accuracy of the information submitted in every entry. If a regulated product is exempt from the applicable testing requirements, the importer would enter a disclaim code in the PGA Message Set (but would still have to complete the eFiling).

Preparing for compliance

The CPSC has published a "quick start guide" for importers,[7] which advises a three-step process for importers preparing for eFiling compliance:

- **Learn, Define, Communicate:** Learn about the eFiling system and how to adjust to the new requirements, inform and collect date from supply chain stakeholders, define compliance roles, identify challenges, and prepare for implementation. Determine which approach to eFiling is preferable.
- **Integration and Development:** Establish needed communication channels with manufacturers and certification testers to gather the required data and then with the customs brokers to transmit the data to CBP. Importers and brokers may need to update their shipment management software to interconnect with the new filing systems. Companies may also need to update supplier contracts to permit the transfer of the required data between parties.
- **Implementation and Improvement:** Enter the compliance data with import documentation, updating as needed for certification and manufacturer changes.

Voluntary eFiling and test runs

In summer 2024, the CPSC unveiled a voluntary version of the eFiling system, allowing importers to begin adoption early.[8] Participants will obtain access to the CPSC Product Registry and the eFiling system. In recent public engagements, the CPSC has informed importers to contact it directly to join the program's waitlist and advised that companies should begin preparing now for compliance with mandatory filing (including by participating in the

[7] "eFiling Quick Start Guide," CPSC, July 2024, accessible here: https://www.cpsc.gov/s3fs-public/eFiling_Quick_Start_Guide.pdf.

[8] "Electronic Filing of Certificate of Compliance Data: Announcement of Expansion of PGA Message Set Test and Request for Additional Participants," 89 FR 47922 (June 4, 2024), accessible here: https://www.federalregister.gov/documents/2024/06/04/2024-12194/electronic-filing-of-certificate-of-compliance-data-announcement-of-expansion-of-pga-message-set; "Electronic Filing of Certificate of Compliance Data: Announcement of Expansion of Partner Government Agency Message Set Test and Collection of Information Burden Estimate," 89 FR 73392 (September 10, 2024), accessible here: https://www.federalregister.gov/documents/2024/09/10/2024-20367/electronic-filing-of-certificate-of-compliance-data-announcement-of-expansion-of-partner-government.

voluntary stage).[9] Importers will be allowed into the voluntary stage from the waitlist on a first come, first served basis on a rolling monthly schedule. Participation is limited to 2,000 companies.

The CPSC ran a beta pilot of the system with 37 importers before beginning the voluntary stage. The tests were run to inform the final rulemaking process and test the filing system. Large importers, including major retailers, have participated in the tests and provided feedback. The beta pilot came after an alpha pilot in 2016 and 2017. Eight volunteer importers successfully filed a limited set of enforcement data through the eFiling system during the alpha.

Implementation schedule

The CPSC is currently developing the final rule, updating the SNPRM in response to public comments and lessons from the beta testing. The CPSC will likely issue the final rule around the end of 2024 or early 2025 (final issuance of the rule depends on a vote by the CPSC commissioners).

With the final rule nearing completion, the CPSC expects that full eFiling implementation would occur "in or around 2025." The SNPRM proposes the mandatory reporting requirement would enter effect 120 days after the issuance of that final rule. The timeline is based on experiences during the beta test, and the CPSC noted it is open to input from other beta participants about implementation timelines as it considers the final effective date. Importers have raised concerns about the implementation timeline in responses to the SNPRM, arguing that (i) technical challenges encountered in the beta pilot will require more time to resolve and (ii) renegotiating contracts and modifying company database systems to transmit the required data are time consuming processes.

USTR Considers Trade Restrictions on China Over Wildlife Trafficking Concerns

On October 15, 2024, the United States Trade Representative (USTR), Department of State, and Department of the Interior published a request for comments (RFQ) for potential new import prohibitions targeting products from China.[10] The RFQ alleges that the Chinese government is underenforcing the Convention on International Trade in Endangered Species of Wild Fauna and Flora's (CITES) prohibition on the international commercial trade of pangolins. Section 8(b) of the Fishermen's Protective Act of 1967 (known as the "Pelly Amendment") empowers the US president to respond to wildlife conservation treaty violations by foreign governments with trade sanctions.[11] The US government has not yet reached a final decision on whether to impose the suggested import prohibitions.

The Pelly Amendment

The Pelly Amendment instructs the executive branch to monitor the implementation of international fishery and endangered species protection programs and report non-compliance to Congress. If the relevant executive branch agencies certify a foreign violation of fishery conservation programs or "trade or taking which diminishes the effectiveness of any international program for endangered or threatened species," then the president may "prohibit the bringing or the importation into the United States of any products from the offending country for any duration as the President determines appropriate and to the extent that such prohibition is sanctioned by the World Trade Organization or the multilateral trade agreements."

The law defines "international program for endangered or threatened species" as any "ban, restriction, regulation, or other measure in effect pursuant to a multilateral agreement which is in force with respect to the United States, the

[9] "Office of Import Surveillance eFiling Implementation Newsletter," Fiscal Year 2024 Quarter 3, accessible here: https://www.cpsc.gov/s3fs-public/eFiling_Newsletter_June%202024_Edition_FINAL.pdf.

[10] "Request for Comments on Potential Import Prohibitions on Certain Products From the People's Republic of China Pursuant to the Pelly Amendment," 89 FR 83073 (October 15, 2024), accessible here: https://www.federalregister.gov/documents/2024/10/15/2024-23639/request-for-comments-on-potential-import-prohibitions-on-certain-products-from-the-peoples-republic.

[11] 22 U.S.C. 1978, accessible here: https://www.federalregister.gov/documents/2024/10/15/2024-23639/request-for-comments-on-potential-import-prohibitions-on-certain-products-from-the-peoples-republic.

purpose of which is to protect endangered or threatened species of animals." CITES is an international program for endangered or threatened species under the definition.

Aggressive use of the Pelly Amendment's import prohibition authority is uncommon. In 1994, the United States used the prohibition authority for the first time in a case involving tiger and rhino trade in Taiwan. The action prohibited the import of all wildlife products from Taiwan, affecting about $22 million in annual trade.[12] The United States revoked the trade prohibition in 1995 after Taiwan strengthened its wildlife trafficking laws.[13] The United States declined to impose trade restrictions on China in a concurrent case in 1994, saying Beijing had recently made progress in reducing tiger and rhino parts trade.

Though the Department of the Interior has issued certifications targeting other countries before and since 1994, the president has not imposed import prohibitions in any other case. Presidents have instead preferred to rely on non-trade measures, such as diplomatic engagement and law enforcement capacity building assistance. For example, in response to a 1995 Pelly Amendment certification targeting whaling activities in Japan, the Clinton administration directed the Department of State to pursue diplomatic engagement.[14] President Clinton's notification to Congress stated that he did "not believe that the use of trade sanctions is the most constructive approach to resolving our differences over research whaling activities with the Government of Japan."

RFQ on China's pangolin trade

Pursuant to the Pelly Amendment's process for pressuring countries to comply with international programs for endangered or threatened species, the RFQ announces the "president now is considering whether to direct the Secretary of the Treasury to prohibit the importation of certain products" from China. The president's determination would be based on the advice of USTR, the Department of State, and the Department of the Interior, including information that the agencies gather from the public through the RFQ.

The law gives the president full discretion over whether and how to impose import prohibitions and – as described above – use of the authority is rare. The Biden administration has not yet decided whether to implement trade restrictions, or decided what products the trade restrictions would target. The RFQ simply notes that the Biden administration is evaluating the "scope and implications of potential import prohibitions."

The Pelly Amendment's extensive presidential discretion also opens questions about what kinds of products the import prohibition may target. The import prohibition does not have to apply specifically to products made from the protected wildlife. The president could establish broader trade restrictions on other industries and products. For example, in the Taiwan case, the Clinton administration's import prohibitions targeted wildlife products that were unrelated to rhinos and tigers. Imports of (i) reptile leather shoes, handbags, and other reptile leather articles and products; (ii) jewelry made from coral, mussel shells, and bone; (iii) edible frogs' legs; (iv) live goldfish and tropical fish for the aquarium trade; and (v) bird feathers, down, and specimens were all subject to the prohibition.

The RFQ requests public input on the proposal, asking "interested persons to submit comments concerning whether and what import prohibition is appropriate, specifically regarding economic and environmental effects of any such prohibitions." The agencies are seeking detailed information, rather than just whether stakeholders support the action. To that end, the RFQ asks commenters to address the following questions:

[12] "Imposition of Prohibitions Pursuant to Section 8(a)(4) of the Fishermen's Protective Act of 1967, as Amended," 59 FR 40463 (August 9, 1994), accessible here: https://www.federalregister.gov/documents/1994/08/09/94-19524/imposition-of-prohibitions-pursuant-to-section-8a4-of-the-fishermens-protective-act-of-1967-as.

[13] "Termination of the Pelly Amendment Certification of Taiwan," 62 FR 23479 (April 30, 1997), accessible here: https://www.govinfo.gov/content/pkg/FR-1997-04-30/pdf/97-11092.pdf.

[14] 1996 Public Papers 205 - Message to the Congress on Japanese Whaling Activities, accessible here: https://www.govinfo.gov/app/details/PPP-1996-book1/PPP-1996-book1-doc-pg205/summary.

- "Whether to prohibit the importation of any product(s) of the PRC pursuant to the certification under the Pelly Amendment that PRC nationals are engaging in trade or taking of pangolins that diminishes the effectiveness of CITES."
- "What product(s) to prohibit."
- "The degree to which prohibiting the importation of any particular product might have a positive or negative economic or environmental effect."
- "Actions other than import prohibitions that would help bring about an end to illegal trade in these imperiled species."

The deadline for submitting public comments is November 14, 2024. Interested stakeholders may submit comments to the docket on the Federal eRulemaking Portal at regulations.gov. The RFQ includes further instructions on how to participate.

Pelly Amendment certification on China's pangolin trade

The RFQ is the latest step in an ongoing effort to pressure the Chinese government to crack down on the illegal international trafficking of endangered pangolins and pangolin parts. The 17th meeting of the Conference of the Parties to CITES (CoP17) raised all species of pangolin to the CITES Appendix I list in 2017, which prohibits all commercial international trade of wild-taken specimens of the listed species.[15] Despite the upgraded level of protection, illegal trade in pangolins has risen in recent years. Most of the illegal international pangolin trade is supplying consumers in China.

The Pelly Amendment certification process began in response to a petition by the Center for Biological Diversity, International Environmental Law Project, and Environmental Investigation Agency UK, filed in 2020.[16] The petition specifically asked the United States to "impose Pelly trade sanctions unless China takes meaningful and substantiated legal action to halt pangolin trade."

The Department of the Interior notified the President and Congress that it had issued a Pelly Amendment certification for the Chinese pangolin trade on August 24, 2023 because "nationals of the People's Republic of China (PRC) are diminishing the effectiveness of CITES by engaging in trade or taking of pangolin species."[17] The Department of the Interior's statement noted that "the Department endeavors to continue diplomatic engagement with the PRC to further pangolin protection" and the president would notify Congress of any action taken within 60 days.

The Biden administration provided the required Congressional notification on November 3, 2023.[18] According to the White House statement, the administration had asked China to "demonstrate its commitment to pangolin conservation and compliance with CITES directives" by closing the domestic pangolin parts market, transparently account for domestic stockpiles, and remove pangolin parts from the national list of approved medicines. The statement noted that China had made progress toward meeting its commitments, but that more time was needed for discussions and monitoring. President Biden directed the Departments of State and Interior to continue engaging with

[15] Conf. 17.10 (Rev. CoP19), Conservation of and trade in pangolins, accessible here: https://cites.org/sites/default/files/documents/COP/19/resolution/E-Res-17-10-R19.pdf.

[16] "Legal Petition Urges U.S. to Certify That China's Pangolin Trade Violates Wildlife Treaty," Center for Biological Diversity, August 6, 2020, accessible here: https://biologicaldiversity.org/w/news/press-releases/legal-petition-urges-us-to-certify-that-chinas-pangolin-trade-violates-wildlife-treaty-2020-08-06.

[17] "Statement from the Department of the Interior on a Pelly Certification," Department of the Interior, September 8, 2023, accessible here: https://www.doi.gov/pressreleases/statement-department-interior-pelly-certification.

[18] "Message to the Congress — Notification to the Congress Consistent With Section 8 of the Fishermen's Protective Act of 1967, as amended (22 U.S.C. 197)," White House, November 3, 2024, accessible here: https://www.whitehouse.gov/briefing-room/presidential-actions/2023/11/03/message-to-the-congress-notification-to-the-congress-consistent-with-section-8-of-the-fishermens-protective-act-of-1967-as-amended-22-u-s-c-197/.

China, including at the November 2023 CITES Standing Committee meeting. The statement concluded by saying the United States would "direct certain prohibitions on the importation of, and impose trade measures on, certain products from the PRC" if China did not implement the desired measures by December 31, 2023. The October 15 RFQ is the latest step toward potentially imposing those prohibitions.

Pelly Amendment certification of Mexico's totoaba and vaquita trade

The Department of the Interior also issued a notification targeting Mexico for illegal takings and trade of totoaba fish and vaquita porpoises in 2023.[19] The Department of the Interior had agreed to finalize the certification as part of a lawsuit settlement with the Center for Biological Diversity and several other wildlife protection groups.[20] The wildlife protection groups filed a petition in 2014 seeking Pelly Amendment certification and trade restrictions targeting Mexico,[21] which they accused the Department of the Interior of unreasonably delaying.

The president's notification to Congress on the Mexico certification noted that the United States is in engaged with Mexico on the concerns and that Mexico has submitted a CITES Compliance Action Plan to the CITES Secretariat.[22] Arguing the ongoing actions have been insufficient, the statement notes that the president has directed the executive branch agencies to continue discussions with Mexico on adopting additional actions, aid Mexican enforcement efforts, and assess Mexico's compliance efforts in July 2024. Like most other previous Pelly Amendment cases (and unlike the China pangolin case), the statement also said the president had decided not to impose trade prohibitions on Mexico.

Biden Administration Proposes Shortening "Buy America" Exception List

On October 21, 2024, the Biden administration announced its intention to substantially shorten the list of products excepted from federal procurement "Buy America" requirements due to their domestic unavailability.[23] The action is the latest development in the Biden administration's ongoing efforts to increase market access restrictions in US government procurement, which began in the first week of the Biden administration with the issuance of Executive Order (EO) 14005, "Ensuring the Future Is Made in All of America by All of America's Workers."[24]

Following the White House announcement, the Department of Defense (DoD), General Services Administration (GSA), and the National Aeronautics and Space Administration (NASA) (the agencies comprising the Federal Acquisition Regulatory Council (FAR Council)) issued the Notice of Proposed Rulemaking (NPRM) that would

[19] "Statement from the Interior Department on a Pelly Certification," Department of the Interior, May 26, 2023, accessible here: https://www.doi.gov/pressreleases/statement-interior-department-pelly-certification.

[20] *Center For Biological Diversity, et al., v. Deb Haaland, et al.*, accessible here: https://www.biologicaldiversity.org/species/mammals/vaquita/pdfs/2023-04-06-Settlement-Center-v-Haaland-22-339-FINAL-SIGNED-Pltfs-and-Defs.pdf.

[21] "Petition for Certification of Mexico pursuant to the Pelly Amendment for Trade in Violation of the Convention on International Trade in Endangered Species," Center for Biological Diversity, September 29, 2014, accessible here: https://www.biologicaldiversity.org/species/mammals/vaquita/pdfs/Totoaba_Pelly_Petition_9_29_14.pdf.

[22] "Letters to the Speaker of the House and the President of the Senate on the Notification to the Congress Regarding the Secretary of the Interior's Certification Under Section 8 of the Fisherman's Protective Act of 1967, as amended," White House July 17, 2023, accessible here: https://www.whitehouse.gov/briefing-room/statements-releases/2023/07/17/letters-to-the-speaker-of-the-house-and-the-president-of-the-senate-on-the-notification-to-the-congress-regarding-the-secretary-of-the-interiors-certification-under-section-8-of-the-fisherman/.

[23] "Biden- Harris Administration Proposes to Further Strengthen "Made in America" with Shortest Exception List in History," White House, October 21, 2024, accessible here: https://www.whitehouse.gov/omb/briefing-room/2024/10/21/fact-sheet-biden-harris-administration-proposes-to-further-strengthen-made-in-america-with-shortest-exception-list-in-history/.

[24] Executive Order 14005 of January 25, 2021: Ensuring the Future Is Made in All of America by All of America's Workers, 86 FR 7475 (January 28, 2021), accessible here: https://www.federalregister.gov/documents/2021/01/28/2021-02038/ensuring-the-future-is-made-in-all-of-america-by-all-of-americas-workers.

implement the changes to the list of domestically nonavailable articles at 25.104(a) of the Federal Acquisition Regulation (FAR).[25] The proposed rule would remove 70 of the 109 articles from the exception list.

Articles to be removed from the list

As instructed by the Biden administration, the FAR Council worked with the new Made in America Office and the Office of Federal Procurement Policy to evaluate each of the 109 articles on the existing list, seeking to remove as many as possible. This is a new approach to managing the list. Typically, the FAR Council relies on public comment from interested industries in determining what products should be on the list. The White House describes this new review process as "a general reset of the list to remove a presumption of nonavailability, encouraging further market research and sending a clear signal to industry." Besides removing articles for which the Biden administration has industrial planning interests, or that it believes have domestic sources, this new review process also allowed the FAR Council to remove articles that are no longer in use.

The FAR Council is proposing to remove articles that qualify under four proposed criteria:

1. **Demonstrated domestic capacity to source the article:** The listed articles that meet this condition are petroleum, crude oil, unfinished oils, and finished products; cadmium; talc, block, steatite; beef, corned, canned; beef extract; leather, sheepskin, hair type; sugars, raw; and yeast, active dry and instant active dry.

2. **Implementation of shorter-duration waivers with centralized oversight would offer valuable insights into government supply chains, particularly articles crucial for national or economic security:** The listed articles that meet this condition are bauxite; cobalt, in cathodes, rondelles, or other primary ore and metal forms; diamonds, industrial; goat hair canvas; goat and kidskins; graphite, natural, crystalline, crucible grade; iodine, crude; manganese; mica; microprocessor chips (brought onto a Government construction site as separate units for incorporation into building systems during construction or repair and alteration of real property); nickel, primary, in ingots, pigs, shots, cathodes, or similar forms, nickel oxide and nickel salts; olive oil; olives (green), pitted or unpitted, or stuffed, in bulk; platinum and related group metals, refined, as sponge, powder, ingots, or cast bars; tantalum; and tungsten.

3. **Limited government demand**: The listed articles that meet this condition are acetylene, black; agar, bulk; chalk, English; anise; bephenium hydroxynaphthoate; calcium cyanamide; castor beans and castor oil; chicle; cinchona bark; colchicine alkaloid, raw; copra; crane rail (85-pound per foot); cryolite, natural; dammar gum; emetine, bulk; ergot, crude; erythrityl tetranitrate; hand file sets (Swiss pattern); handsewing needles; lac; lavender oil; menthol, natural bulk; nux vomica, crude; oiticica oil; opium, crude; pine needle oil; pyrethrum flowers; quebracho; quinidine; quinine; rabbit fur felt; radium salts, source and special nuclear materials; rosettes; secretin; shellac; thread, metallic (gold); thyme oil; triprolidine hydrochloride; wax, carnauba; wire glass; woods, logs, veneer, and lumber of Alaskan yellow cedar, angelique, balsa, ekki, greenheart, lignum vitae, mahogany, and teak; and 50 denier rayon yarn.

4. **Believed to be obsolete:** The listed articles that meet this condition are asbestos, amosite, chrysotile, and crocidolite; ipecac, root; kauri gum; and santonin, crude.

The NPRM neither describes the standards the listed articles had to fulfil to meet these four conditions, nor does it describe the reasoning behind the FAR Council's decisions for each specific article.

The US government spends a relatively small amount of its procurement budget on these articles. According to the NPRM, total acquisition spending amounted to less than $150 million through 10,000 contract actions in fiscal year 2023 (excluding the oil products). In contrast, overall US federal procurement spending is around $750 billion per

[25] "Federal Acquisition Regulation: List of Domestically Nonavailable Articles," 89 FR 84505 (October 23, 2024), accessible here: https://www.federalregister.gov/documents/2024/10/23/2024-24395/federal-acquisition-regulation-list-of-domestically-nonavailable-articles.

year. The NPRM also notes that about half of these articles have not been acquired in significant quantity in any recent year.

Articles remaining on the list

Following the NPRM's update, the new list of 39 nonavailable articles at FAR 25.104(a) would include antimony, as metal or oxide; bamboo shoots; bananas; bismuth; books that are not printed in the United States; brazil nuts, unroasted; capers; cashew nuts; chestnuts; chrome ore or chromite; cocoa beans; coconut and coconut meat, unsweetened, in shredded, desiccated, or similarly prepared form; coffee, raw or green bean; cork, wood or bark and waste; cover glass, microscope slide; fair linen, altar; fibers of abaca, abace, agave, coir, flax, jute, jute burlaps, palmyra, and sisal; grapefruit sections, canned; hemp yarn; hog bristles for brushes; hyoscine, bulk; modacrylic fiber; nitroguanidine (picrite); oranges, mandarin, canned; pineapple, canned; quartz crystals; rubber, crude and latex (natural); rutile; silk, raw and unmanufactured; spare and replacement parts for equipment of foreign manufacture, and for which domestic parts are not available; spices and herbs, in bulk; swords and scabbards; tapioca flour and cassava; tartar, crude and tartaric acid and cream of tartar in bulk; tea in bulk; tin in bars, blocks, and pigs; vanilla beans; cobra venom; and water chestnuts.

Alternative waiver approaches

Federal contracting officials will still be able to seek individual waivers for the delisted articles, providing an alternative route for foreign suppliers to continue accessing the US government procurement market. Generally, contracting agencies would publish proposed Buy America waivers to the *Federal Register* for public comments, then publish a final waiver after gathering public input, for each acquisition contract. If a procuring agency establishes that domestic supply will remain insufficient for a given article, then the agency can also seek a time-bound multi-procurement waiver.

For many articles removed from the list, specific waivers will be necessary. As the NPRM shows, most of the articles proposed for removal from the list are being removed for industrial planning purposes, instead of due to new demonstrated domestic availability. Forcing contractors into the more cumbersome individual waiver process is the intended effect of the proposed changes, with the FAR Council predicting that the added regulatory processes will encourage onshoring. The NPRM states that "use of individualized waivers in lieu of regulatory waivers that are coordinated centrally and posted for public awareness should encourage the type of ongoing, proactive engagement with industry to understand supply chains and market trends that is vital to strengthening domestic manufacturing and reducing the need for [nonavailability] waivers over time."

Acquisition of covered articles that are sourced from free trade agreement partners or countries that are party to the WTO Agreement on Government Procurement (GPA) would also remain allowed.

Call for public comments

The FAR Council is accepting public feedback on the NPRM until December 23, 2024. The *Federal Register* notice includes instructions on how interested stakeholders can submit feedback via the Federal eRulemaking portal at regulations.gov.

Additional opportunities to provide feedback on the list will be available. The FAR instructs that the domestic nonavailability list should be published to the Federal Register every five years for public comment. Stakeholders can also submit recommendations to remove a specific item from the list at any time.

US Issues Proposed Rule Limiting Sensitive Data Transactions

On October 21, 2024, the US Department of Justice (DOJ) announced the Notice of Proposed Rulemaking (NPRM) for regulations that would restrict transfer of certain bulk US sensitive personal data and US government data to

foreign entities associated with China and other countries of concern.[26] The key points in the NPRM remain unchanged from the original proposal the Biden administration issued in late February 2024, though the NPRM provides more complete details and explanations of the proposed restrictions. The most significant revisions involve clarifications to the exemption on financial services data transfers and new exemptions for routine communication services and clinical trial data.

Overview of the proposed rule

The NPRM builds on the Advance Notice of Proposed Rulemaking (ANPRM) the DOJ issued in late February 2024 to implement President Biden's Executive Order 14117 on "Preventing Access to Americans' Bulk Sensitive Data and United States Government-Related Data by Countries of Concern" (EO).[27] The EO called for the DOJ to promulgate regulations to prevent the large-scale transfer of sensitive personal data and US Government-related data to "countries of concern" (*i.e.*, China, Russia, Iran, North Korea, Cuba, and Venezuela), and impose security requirements on vendor agreements. After issuing the ANPRM, the DOJ received 67 comments and met with over 100 stakeholder groups.

To implement the EO, the NPRM proposes to prohibit or restrict US persons from transferring certain US government-related data or US bulk sensitive personal data to covered persons from countries of concern. To implement this set of prohibitions, restrictions, and related security measures, the NPRM (i) defines the types of covered sensitive personal data and the bulk data thresholds; (ii) identifies the classes of restricted and prohibited data transactions (collectively, "covered data transactions"); (iii) identifies the countries of concern and covered persons; (iv) establishes licensing and advisory opinion processes; (v) establishes recordkeeping, reporting, and due diligence obligations; (vi) and establishes enforcement mechanisms.

Sensitive personal data: The NPRM sets out six categories of "sensitive personal data," all of which are defined in the NPRM in detail:

1. Certain covered personal identifiers.
2. Precise geolocation data.
3. Biometric identifiers.
4. Human genomic data.
5. Personal health data.
6. Personal financial data.

The NPRM would create several categorical exclusions for certain types of data, including (i) public or nonpublic data that do not relate to an individual (including, trade secrets and proprietary information), (ii) data already lawfully publicly available from government records or widely distributed media, (iii) personal communications, and (iv) certain information and informational materials.

[26] "Provisions Pertaining to Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," 89 FR 86116 (October 29, 2024), accessible here: https://www.federalregister.gov/documents/2024/10/29/2024-24582/provisions-pertaining-to-preventing-access-to-us-sensitive-personal-data-and-government-related-data; and "Justice Department Issues Comprehensive Proposed Rule Addressing National Security Risks Posed to U.S. Sensitive Data," DoJ, October 21, 2024, accessible here: https://www.justice.gov/opa/pr/justice-department-issues-comprehensive-proposed-rule-addressing-national-security-risks.

[27] "National Security Division; Provisions Regarding Access to Americans' Bulk Sensitive Personal Data and Government-Related Data by Countries of Concern," 89 FR 15780 (March 5, 2024), accessible here: https://www.federalregister.gov/documents/2024/03/05/2024-04594/national-security-division-provisions-regarding-access-to-americans-bulk-sensitive-personal-data-and; and Executive Order 14117 of February 28, 2024 "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern," 89 FR 15421 (March 1, 2024), accessible here: https://www.federalregister.gov/documents/2024/03/01/2024-04573/preventing-access-to-americans-bulk-sensitive-personal-data-and-united-states-government-related.

The NPRM does not exclude anonymized, pseudonymized, de-identified, or encrypted sensitive personal data from coverage. National security officials are concerned about the potential for improving data analysis tools to allow identification of individuals from data that is presently considered less sensitive, including data previously thought to be anonymized or encrypted. Regardless of the initial definitions adopted, concerns about the expanding scope of sensitive data and the broad language used to establish the covered data categories in the EO mean the types of data subject to the rule can — and likely will — increase over time. According to the NPRM, the DOJ is already considering adding other forms of human 'omic data to final rule, which may include epigenomic data, glycomic data, lipidomic data, metabolomic data, meta-multiomic data, microbiomic data, phenomic data, proteomic data, and transcriptomic data.

Bulk sensitive personal data thresholds: The proposed prohibitions and restrictions would only apply to covered data transactions that involve volumes of sensitive personal data that exceed certain bulk thresholds. The proposed rule would establish the following bulk thresholds: human genomic data on over 100 US persons, biometric identifiers on over 1,000 US persons, precise geolocation data on over 1,000 US devices, personal health data on over 10,000 US persons, personal financial data on over 10,000 US persons, certain covered personal identifiers on over 100,000 US persons.

US government related data: The bulk data thresholds would not apply to transactions of sensitive personal data that involve certain data related to US government personnel. The rule proposes that two types of data would be defined as US government related data and subjected to the relevant prohibitions or restrictions regardless of transaction volume:

- Precise geolocation data within certain listed geographic areas. The NPRM lists specific government-related locations that are included under this category. The list proposed in the NPRM includes eight intelligence community-related facilities but is not yet comprehensive. The DOJ intends to add other facilities in the final rule's list.
- Any sensitive personal data marketed as linked to current or recent former government employees or contractors. The NPRM provides more clarity than the ANPRM on the definition of recent former government employees, explaining the rule would apply to employees or contractors who have worked for the US government in the past two years and that former senior officials will be defined according to existing ethics regulations.

Covered data transactions: The NPRM establishes four categories transactions that involve transfers of data that would be subject to the rule's prohibitions or restrictions, referred to as the "covered data transactions." Covered data transactions are transactions that involve access to any US government related data or bulk US sensitive personal data that involve (i) data brokerage, (ii) vendor agreements, (iii) employment agreement; or (iv) an investment agreements.

Classes of exempt transactions: The rule would exempt certain types of transactions from the prohibitions and restrictions:

- Personal communications that are not transferring anything of value, informational materials involving expressive materials, and travel information;
- Official US government activities;
- Financial services transactions that are incident to and part of providing financial services, including transferring data for e-commerce transactions and investment management services;
- Routine internal corporate group transactions (this exception would not apply to third-party vendors that engage in a corporation's routine business activities);
- Transactions required or authorized by Federal law or international agreement;

- Investment agreements already subject to mitigation agreements through the Committee on Foreign Investment in the United States (CFIUS) review process;
- Transactions incident to the provision of telecommunications services;
- Data transactions necessary for drug, biological product, and medical device regulatory authorizations; and
- Other clinical investigations and post-marketing surveillance data if the transactions are part of clinical investigations regulated by the Food and Drug Administration (FDA).

The clinical trial and telecommunications exceptions are new additions in the NPRM, which DOJ developed in response to stakeholder feedback. The financial services exception has also been broadened.

Prohibited transactions: The proposed rule prohibits two types of covered data transactions:

- **Data brokerage** transactions with a country of concern or a covered person are prohibited. Data brokerage is broadly defined to include the sale of data, licensing of access to data, or other similar commercial transactions involving transfer of data to a recipient that did not collect or process the data directly from the individuals lined to the data.
- Any covered data transaction involving access to bulk **human genomic data** and biospecimens from which genomic data could be derived. This prohibition would apply to any covered data transactions that involve access to bulk human genomic data or human biospecimens from which bulk human genomic data can be derived, even when the transactions would otherwise only be restricted.

Restricted transactions: The other three classes of covered data transactions — vendor agreements, employment agreements, and investment agreements — are designated as restricted transactions (unless such a transaction includes human genomic data). Unlike prohibited transactions, restricted transactions would be allowed if the persons involved meet certain data security requirements.

Restrictions on foreign counterparties: To address the risk of data being resold or transferred through third parties, the rule would require US persons engaged in data brokerage transactions with any foreign person to satisfy certain security conditions. Foreign persons will need to enter contracts that prohibit reselling or providing access to that data to a country of concern or covered person.

Countries of concern, covered persons, and designation of covered persons: The NPRM would regulate covered data transactions between “US persons” and “covered persons.” Generally, covered persons are persons that have an unacceptable risk of transferring the covered data to the designated countries of concern. The covered countries of concern are China (including Hong Kong and Macau), Cuba, Iran, North Korea, Russia, and Venezuela.

The NPRM proposes four classes of covered persons:

1. Foreign entities that are 50% or more owned by a country of concern, organized under the laws of a country of concern, or has its principal place of business in a country of concern.
2. Foreign entities that are 50% or more owned by a covered person.
3. Foreign employees or contractors of countries of concern or entities that are covered persons.
4. Foreign individuals primarily resident in countries of concern.

The NPRM would also give the DOJ authority to designate specific persons as covered persons. Under the designation provision, the DOJ may designate persons as covered persons, if it determines them to be (i) owned or controlled by or subject to the jurisdiction of a country of concern or another covered person; (ii) acting or likely to act

on behalf of a country of concern or another covered person; or (iii) are knowingly causing or directing a violation of the regulation. DOJ can designate US persons and persons in countries that are not countries of concern as covered persons through this system.

US Persons: A United States Person is a US citizen, national, or other lawful resident; an entity organized solely under the laws of the United States or any jurisdiction within the United States (including foreign branches); or any person in the United States. Though foreign branches of companies organized under US law are US persons, foreign subsidiaries of US companies that are organized under the laws of the foreign country are considered foreign persons. Similarly, a subsidiary of a foreign corporation (which is a foreign person) that is organized under US law would be a US person.

Licenses authorizing certain prohibited transactions: Under certain specified conditions, DOJ can issue general licenses to authorize transactions that are otherwise prohibited, which it would publish to the *Federal Register*. DOJ could also issue specific licenses for specific transactions by a single party that would otherwise be otherwise prohibited.

Advisory opinions: DOJ can issue advisory opinions in response to questions from regulated persons about specific transactions.

Due diligence obligations, reporting, and recordkeeping: The NPRM instructs companies to develop and implement internal compliance programs for complying with the regulation. The rule would not prescribe specific due diligence, recordkeeping, or reporting obligations across all companies. Instead, DOJ enforcement actions would consider the adequacy of a company's internal compliance programs when investigating violations. In some situations, though, the rule would require reporting to DOJ. Reports may be required for situations involving certain cloud-computing services, solicitation of prohibited data brokerage transactions, suspicion that a foreign counterparty has transferred covered data to a covered person, transferring data for regulatory approvals of drugs. US persons engaging in restricted transactions would also face specific compliance and recordkeeping obligations under the CISA security standards.

Call for public comments

The NPRM will be open to public comment through November 29, 2024. Interested stakeholders may submit comments to the docket on the Federal eRulemaking Portal at regulations.gov. The NPRM includes further instructions on how to participate. Participating in the public comment process can help shape the outcome of the action and prompt the government to further clarify its actions. The DOJ will not issue its final rule until it has reviewed and responded to the feedback received.

CISA security standards

The NPRM would require that vendor agreements, employment agreements, and investment agreements that qualify as restricted transactions adopt specific security requirements. The Department of Homeland Security's Cybersecurity and Infrastructure Security Agency (CISA) is creating those security requirements through a separate rulemaking process. CISA published the proposed security requirements on October 21, 2024, alongside the DOJ NPRM.[28] The CISA proposal lays out a series of organizational-level, system-level, and data-level requirements. The requirements link to relevant National Institute of Standards and Technology (NIST) cybersecurity and privacy framework provisions, as well as the CISA Cross-Sector Cybersecurity Performance Goals.

[28] "Proposed Security Requirements for Restricted Transactions," CISA, October 21, 2024, accessible here: https://www.cisa.gov/resources-tools/resources/proposed-security-requirements-restricted-transactions; and "Request for Comment on Security Requirements for Restricted Transactions Under Executive Order 14117," 89 FR 85976 (October 29, 2024), accessible here: https://www.federalregister.gov/documents/2024/10/29/2024-24709/request-for-comment-on-security-requirements-for-restricted-transactions-under-executive-order-14117.

CISA is seeking public input on the proposed security requirements on the Federal eRulemaking docket at regulations.gov. The deadline for submitting comments is November 29, 2024.

Overlap with the Protecting Americans' Data from Foreign Adversaries Act

The DoJ's proposed rule is one of two overlapping international data transaction restrictions the United States developed in 2024. The other measure is the Protecting Americans' Data from Foreign Adversaries Act Of 2024 (PADFAA), which passed into law on April 24, 2024 as Division I of H.R. 815.[29] How the US government intends to manage the two similar (but not identical) systems remains unclear.

The PADFAA directs the Federal Trade Commission (FTC) to enforce its data brokerage prohibitions through civil enforcement actions for unfair and deceptive business practices under the Federal Trade Commission Act. The law entered force on June 23, 2024, with little further clarification from regulators. The FTC will likely use enforcement actions to demonstrate how it intends to interpret the law, rather than issue detailed regulations.

The PADFAA prohibits a "data broker" from selling other otherwise making available "personally identifiable sensitive data of a United States individual" to any foreign adversary country (i.e., China, Iran, North Korea, and Russia) or any entity controlled by a foreign adversary. "Controlled by a foreign adversary" is defined to include entities in which any person or entity domiciled or headquartered in, or organized under the laws of, a foreign adversary owns, directly or indirectly, "at least a 20 percent stake." The exact extent of the law's intended scope is subject to debate. The PADFAA's definition of "sensitive data" is significantly broader than the definition in NPRM and its definition of a covered "United States Individual" is unusually vague. The law's focus on regulating "data broker" entities specifically, instead of all data brokerage transactions by US persons, also raises questions about the extent to which the law can actually limit the relevant data transfers.

The DoJ's NPRM discusses the implications of the PADFAA for its own bulk data transfer rules, arguing the PADFAA does not adequately address the data security risks that the Biden administration is attempting to address through the NPRM. The NPRM concludes that the DOJ will not modify the NPRM to account for the PADFAA. The NPRM simply notes that the DOJ and FTC "intend to coordinate closely to ensure that these authorities are exercised in a harmonized way to minimize any conflicting obligations or duplicative enforcement." The Biden administration has also continued to stress the importance of federal comprehensive privacy legislation, urging Congress to pass a privacy bill.

US Treasury Issues Final Rule on Outbound Investment Restrictions

On October 28, 2024, the United States Department of the Treasury (Treasury) issued the final rule to implement outbound investment restrictions on advanced technology businesses in China.[30] The new Outbound Investment Security Program[31] established in the regulation will completely prohibit or require notification for certain US investments in companies engaged in certain activities related to semiconductors and microelectronics, quantum information technology, and artificial intelligence (AI) technologies and have certain associations with China (including Hong Kong and Macau). Transactions with a completion date on or after January 2, 2025 are subject to the rule. Treasury intends to publish more information to its website about notification filing and administrative procedures over the next few months.

[29] H.R.815 - Making emergency supplemental appropriations for the fiscal year ending September 30, 2024, and for other purposes, 118th Congress (2023-2024), accessible here: https://www.congress.gov/bill/118th-congress/house-bill/815/text.

[30] "Treasury Issues Regulations to Implement Executive Order Addressing U.S. Investments in Certain National Security Technologies and Products in Countries of Concern," Treasury, October 28, 2024, accessible here: https://home.treasury.gov/news/press-releases/jy2687; and "Provisions Pertaining to U.S. Investments in Certain National Security Technologies and Products in Countries of Concern," advance copy of the final rule, accessible here: https://home.treasury.gov/system/files/206/TreasuryDepartmentOutboundInvestmentFinalRuleWEBSITEVERSION_0.pdf.

[31] See Treasury's new "Outbound Investment Security Program" for more information and relevant documents, accessible here: https://home.treasury.gov/policy-issues/international/outbound-investment-program.

Given the global interdependence of the technology sector, the new requirements will likely need to be assessed in many investments. The system puts the onus on US persons to determine the application of its requirements to their transactions, including with a knowledge standard requiring due diligence in connection with compliance. To anticipate the potential effect on a given transaction, parties will need to conduct thorough due diligence and plan early for potential regulatory challenges. This careful diligence and planning will be crucial for any US person contemplating investment in China or in Chinese-owned entities outside China. It will be particularly important for large private equity firms and multinational companies that structure their transactions across multiple jurisdictions around the world. Non-US investment funds with US investors and non-US multinational enterprises doing businesses with both US and Chinese persons will also have to carefully review the regulations for any potential exposure.

Development of the rule

The rulemaking process began on August 9, 2023, when President Biden issued an Executive Order[32] (EO) establishing a new program to prohibit certain outbound US investments in China in technology sectors relevant to military, intelligence, surveillance, and cyber-enabled capabilities. Notification of other outbound investments to China in these sectors will also be required. Unlike the inbound foreign investment review process administered by the Committee on Foreign Investment in the United States (CFIUS), the Outbound Investment Security Program does not involve a case-by-case review process for covered transactions. Instead, the new outbound investment controls will either prohibit or require notification for listed investment activities in listed sectors. Though the rule currently only applies to a few narrowly defined technology sectors, the EO represents a major change in US investment policy and could grow in scope over time. Additional changes to the program's scope and coverage could also come from Congress, which is debating similar legislation.

The EO directed the Treasury (which also leads CFIUS) to prepare implementing regulations, for which Treasury issued an Advanced Notice of Proposed Rulemaking (ANPRM) alongside the EO.[33] Treasury issued the full Notice of Proposed Rulemaking (NPRM) and called for additional public feedback on July 5, 2024.[34] The final rule is generally consistent with the NPRM, but makes numerous technical edits, improves the specificity of some definitions, and adds explanatory notes.

Scope and coverage of the rule

To implement the EO, Treasury's final rule explains obligations, definitions, coverage, and compliance processes, as summarized below.

- **US persons subject to the obligations:** A US person includes any US citizen or lawful permanent resident, as well as any entity organized under the laws of the United States or any jurisdiction within the United States, including foreign branches of any such entity, and any person in the United States.
- **Covered foreign persons subject to the transaction restrictions:** A person is a covered foreign person if they are (i) a person of a country of concern engaged in a covered activity related to the defined technologies and products; (ii) a person that has a voting or equity interest, board seat, or certain powers with respect to such a person of a country of concern where more than 50% of one of several key financial metrics of the person is

[32] Executive Order 14105 of August 9, 2023, "Addressing United States Investments in Certain National Security Technologies and Products in Countries of Concern," 88 FR 54867 (August 11, 2024), accessible here: https://www.federalregister.gov/documents/2023/08/11/2023-17449/addressing-united-states-investments-in-certain-national-security-technologies-and-products-in.

[33] "Advance Notice of Proposed Rulemaking: Provisions Pertaining to U.S. Investments in Certain National Security Technologies and Products in Countries of Concern," 88 FR 54961, August 14, 2023, accessible here: https://www.federalregister.gov/documents/2023/08/14/2023-17164/provisions-pertaining-to-us-investments-in-certain-national-security-technologies-and-products-in.

[34] "Provisions Pertaining to U.S. Investments in Certain National Security Technologies and Products in Countries of Concern," 89 FR 55846, July 5, 2024, accessible here: https://www.federalregister.gov/documents/2024/07/05/2024-13923/provisions-pertaining-to-us-investments-in-certain-national-security-technologies-and-products-in.

attributable to one or more such persons of a country of concern; or (iii) a person of a country of concern that participates in a joint venture with a US person if such joint venture engages or intends to engage in a covered activity.

A **person of a country of concern** includes (i) an individual who is a citizen or permanent resident of a country of concern (and not a US citizen or permanent resident); (ii) an entity organized under the laws of, headquartered in, incorporated in, or with a principal place of business in a country of concern; (iii) the government of a country of concern or a person acting for or on behalf of the government of a country of concern; and (iv) an entity that is directly or indirectly at least 50%-owned by any persons or entities in any of the previous categories.

- **Categories of covered transactions:** The transaction prohibitions and notification requirements apply to certain defined transaction types engaged in by US persons (called, "covered transactions"), which include:
  - the acquisition of an equity interest or contingent equity interest;
  - certain debt financing that affords certain rights to the lender;
  - the conversion of a contingent equity interest;
  - a greenfield investment or other corporate expansion;
  - entrance into a joint venture; and
  - certain investments as a limited partner in a non-US person pooled investment fund.
- **Excepted types of transactions:** Some specified types of transactions that are within the definition of covered transactions are excepted (many of which involve types of transactions in which the US person has limited rights and limited direct involvement in the entity), including:
  - Investments in publicly traded securities;
  - Certain limited partner investments;
  - Investments in derivative securities;
  - Intracompany transactions;
  - Certain syndicated debt financings;
  - Equity-based compensation;
  - Transactions that involve full buyouts of country of concern ownership; and
  - Transactions that are necessary to fulfill uncalled capital commitments that were entered into before January 2, 2025.

Treasury may issue company-specific exceptions if it determines a transaction in question is in the US national interest. The new Outbound Investment Security Program website will provide more information on the application process.

Treasury may also exempt transactions that involve persons in countries that have adopted outbound investment restrictions and corresponding export controls that are similar to those of the United States. Treasury does not expect other countries to adopt identical rules. Instead, Treasury will assess whether the foreign regulatory systems address the same national security risks, including the extent to which it is effectively used to regulate outbound investment in semiconductors, quantum information technologies, and AI; the extent to which the

country can legally prohibit investments; and the extent to which the country's export controls can limit exports in the covered sectors.

The United States has discussed developing outbound investment restrictions with some of its allies and is promoting the policy among the G7. The G7's July 2024 leaders' statement acknowledged the possibility of adopting the system, but did not commit to it, stating "we believe that appropriate measures designed to address risks from outbound investments could be important to complement existing tools of targeted controls on exports and inbound investments."[35] The European Union and the United Kingdom have begun considering adopting comparable systems but are far from implementation.

- **Technologies and products subject to the transaction prohibition and reporting requirements:** The covered transaction prohibition and notification requirements apply only to covered foreign persons engaged in "covered activities," which are certain activities related to specific technologies and products within the semiconductor and microelectronics, quantum information technology, and artificial intelligence industries:

  Semiconductors and microelectronics

  - Prohibited transactions: Covered transactions related to certain electronic design automation software; certain fabrication or advanced packaging tools; the design or fabrication of certain advanced integrated circuits; advanced packaging techniques for integrated circuits; and supercomputers.
  - Notifiable transactions: Covered transactions related to the design, fabrication, or packaging of integrated circuits not otherwise covered by the prohibited transaction definition.

  Quantum information technologies

  - Prohibited transactions: All covered transactions related to the development of quantum computers or production of any critical components required to produce a quantum computer; the development or production of certain quantum sensing platforms; and the development or production of certain quantum networks or quantum communication systems.
  - Notifiable transactions: None. All covered quantum information technologies activities are prohibited.

  AI systems

  - Prohibited transactions: Covered transactions related to the development of any AI system designed to be exclusively used for, or intended to be used for, government intelligence, mass-surveillance, or military end uses. Also, prohibited are any covered transactions related to the development of any AI system trained using a quantity of computing power greater than 10^25 computational operations, or trained using primarily biological sequence data and a quantity of computing power greater than 10^24 computational operations.
  - Notifiable transactions: Covered transactions related to the development of any AI system not otherwise covered by the prohibited transaction definition, where such AI system is designed or intended to be used for government intelligence, mass-surveillance, or military end uses, or that are trained using a quantity of computing power greater than 10^23 computational operations.

- **Other prohibited transactions:** The rule also prohibits covered transactions (even if they would otherwise just be subject to notification requirements) where the covered foreign person (including joint ventures) is listed on the Bureau of Industry and Security's (BIS) Entity List or Military End User List; the Office of Foreign Assets Control's (OFAC) List of Specially Designated Nationals and Blocked Persons (SDN List) or Non-SDN Chinese Military

[35] "G7 Apulia Leaders' Communiqué," June 14, 2024, accessible here: https://www.whitehouse.gov/briefing-room/statements-releases/2024/06/14/g7-leaders-statement-8/.

Industrial Complex List (NS-CMIC List); or is designated as a foreign terrorist organization (FTO) by the Department of State. The prohibition also extends to cases where the covered foreign person meets the definition of a Military Intelligence End-User by BIS as well as covered foreign persons that are 50% or more owned in the aggregate, directly or indirectly, by one or more persons on the SDN List.

- **Process for notifications:** If a transaction is subject to the notification requirements, the US person must submit a notification form to Treasury that includes information related to the transaction, including the US person, the covered foreign person, the covered transaction, and the relevant national security technologies and products. Notification should be filed no later than 30 days after the relevant covered transaction is completed. If the US person acquires knowledge after completing a transaction that should have been a covered transaction, then the US person should submit the notification no later than 30 days after the acquisition of such knowledge.
- **Restriction on knowingly directing an otherwise prohibited transaction:** To address circumvention risks, a US person is also prohibited from knowingly directing a transaction by a non-US person that the US person knows at the time of the transaction would be a prohibited transaction if engaged in by a US person. As a result, US nationals working for non-US companies cannot participate in the types of transactions prohibited under this rule. The final rule provides a system for those US persons working for foreign companies to recuse themselves from participation in those activities.
- **Knowledge standard and expectations for a reasonable and diligent inquiry prior to undertaking a transaction:** US persons are obligated to comply with the rules if they have knowledge that a transaction involves a covered foreign person. The rule considers a US person to have knowledge if they (i) possess actual knowledge that a fact or circumstance exists or is substantially certain to occur, (ii) possess an awareness of a high probability of a fact or circumstance's existence or future occurrence, or (iii) could have possessed such information through a reasonable and diligent inquiry. The final rule sets out criteria, with new clarifications, by which the government would assess whether a US person has met the knowledge standard. To help clarify what it would consider sufficient due diligence by a US person, Treasury added a new section to the final rule stating that it would consider the "totality of relevant facts and circumstances" involving the transaction.
- **Enforcement and penalties:** Violations are subject to civil and criminal penalties under the International Emergency Economic Powers Act (IEEPA). In the event of a violation, Treasury is authorized to impose civil penalties and could also refer criminal violations to the Attorney General. Treasury may also take any action authorized under IEEPA to nullify, void, or otherwise require divestment of any prohibited transaction.

Trade Actions

Section 301

USTR Opens New Section 301 Tariff Exclusion Process for Certain Manufacturing Machinery

On October 15, 2024, the United States Trade Representative (USTR) opened a new tariff exclusion process for imports subject to the Section 301 tariffs on China.[36] Unlike previous exclusion processes that applied to all products subject to the tariffs, only imports of machinery used in domestic manufacturing classified within certain Harmonized Tariff Schedule (HTS) subheadings under Chapters 84 and 85 may qualify under the new exclusions. The eligible HTS subheadings are listed in Annex E of the September 18, 2024 Federal Register Notice (FRN) that implemented the increased Section 301 tariffs.[37]

The new exclusion request process

The procedures for seeking the exclusions are described in a new FRN, circulated by USTR on October 15.[38] Under the system (which is a modified version of the system USTR has used for other exclusion Section 301 exclusions), importers should file the exclusion applications and other comments through the docket on the USTR Comments Portal.[39] Any exclusion granted will be effective starting from the date of publication of the exclusion determination in the *Federal Register* and will extend through May 31, 2025. Importers may apply for exclusions until March 31, 2025.

The FRN describes a four-step process for seeking an exclusion as follows:

1. **The importer applies for an exclusion.** The requests must identify a single specific product from the Annex E list and provide supporting data and rationale for the exclusion. Among other factors, importers would have to document how any equipment considered for an exclusion would be used in domestic manufacturing, whether comparable equipment is available from alternate sources, whether the sector is a recipient of a US federal investment program, and whether the equipment is a target of China's "Made in China 2025" initiative or other industrial program.

2. **A public response period is provided for each application**. Interested third parties will have 30 days from the date a request is posted on the docket to respond to the request, indicating their support or opposition. Objectors would have to explain their relationship to the manufacturing equipment identified, reasons for objecting, whether the manufacturing equipment is available from sources other than China, a description of the alternative available equipment, and whether the objector has attempted to sell the equipment to the organization requesting the exclusion. The original requestors would then have within the later of 15 days after the posting of a response or 15 days after the closing of the 30-day response period to reply to any responses.

3. **USTR reviews the request and any submitted responses**. USTR will begin its review of the exclusion request after the 30+15-day public comment period is complete. USTR intends to evaluate the applications on a case-by-

[36] "USTR Opens Exclusion Process for Certain Machinery Used in Domestic Manufacturing," October 15, 2024, accessible here: https://www.ustr.gov/about-us/policy-offices/press-office/press-releases/2024/october/ustr-opens-exclusion-process-certain-machinery-used-domestic-manufacturing.

[37] *See,* "Annex E—Subheadings Eligible for Machinery Exclusion Process," at "Notice of Modification: China's Acts, Policies and Practices Related to Technology Transfer, Intellectual Property and Innovation," 89 FR 76581 (September 18, 2024), accessible here: https://www.federalregister.gov/documents/2024/09/18/2024-21217/notice-of-modification-chinas-acts-policies-and-practices-related-to-technology-transfer.

[38] "Procedures for Requests to Exclude Certain Machinery Used in Domestic Manufacturing From Actions Pursuant to the Section 301 Investigation of China's Acts, Policies and Practices Related to Technology Transfer, Intellectual Property and Innovation," (October 17, 2024), accessible here: https://federalregister.gov/d/2024-23880.

[39] *See*, "Temporary Exclusions for Machinery Used in Domestic Manufacturing" at the USTR Comments Portal, accessible here: https://comments.ustr.gov/s/.

case basis, "taking into account the asserted rationale for the exclusion, whether the exclusion would undermine the objective of the Section 301 investigation, and whether the request defines the product with sufficient precision."

4. **USTR publishes a granted exclusion to the *Federal Register*.** If USTR denies an exclusion request, it would instead post a denial letter on the docket.

Other available Section 301 exclusions

USTR automatically implemented 14 tariff exclusions for certain solar wafer and cell manufacturing equipment classified within HTS 8486.10.0000, 8486.20.0000, and 8486.40.0030. The exclusions are retroactive and applicable with respect to products that are entered for consumption, or withdrawn from warehouse for consumption, on or after January 1, 2024, and through May 31, 2025. The exclusions are based on product description instead of HTS codes, which are provided in Annex B of the September 18 FRN. A September 26, 2024 customs guidance bulletin describes the entry filing and refund processes for the solar exclusion, as well as the temporary specific exclusions for enteral syringes and certain ship-to-shore gantry cranes.[40]

While the Biden administration's review of the Section 301 tariffs proceeded over the past two years, USTR had maintained 352 general exclusions and 77 COVID-related exclusions to the tariffs. Alongside the completion of the Section 301 review and issuance of the tariff increases in May 2024, USTR announced that 234 of the exclusions would expire on June 14, 2024.[41] The remaining exclusions will remain in effect until May 31, 2025 (the same date on which the manufacturing equipment exclusions under the new Section 301 expansion would expire).

Though all exclusions are set to expire on May 31, 2025, USTR could extend any of the exclusions again at its own discretion. That said, in announcing the May 2024 extension, USTR emphasized that it expects importers to treat the exclusions as temporary and to seek alternative suppliers outside of China.

Petition Seeks Section 301 Trade Restrictions on China Over Fentanyl Trafficking

On October 18, 2024, a petition was filed seeking an investigation under Section 301 of the Trade Act of 1974 of China's acts, policies, and practices related to exports of fentanyl and precursor chemicals.[42] The petition asks that the United States Trade Representative (USTR) restrict trade and investment with China if the Chinese government does not adopt new measures to restrict illegal drug trafficking. USTR confirmed on October 18, 2024 that it had received the petition.[43] Under Section 301, USTR has 45 days from the petition's submission to decide whether to pursue an investigation, which would be December 2, 2024.

The petition

The petition was filed by Facing Fentanyl, a coalition of non-profit groups that represent families of opioid abuse victims.[44] The petition alleges that the Chinese government subsidizes fentanyl-exporting companies, obstructs US law enforcement investigations, and has failed to stop fentanyl exports through its own law enforcement activities. Since Section 301 investigations are intended to be used is response to restrictions on US commerce, the petition

[40] CSMS # 62411889 - Guidance: Section 301 Four-Year Review Modifications, accessible here: https://content.govdelivery.com/bulletins/gd/USDHSCBP-3b85471.

[41] "Notice of Extension of Certain Exclusions: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation," 89 FR 46948 (May 30, 2024), accessible here: https://www.federalregister.gov/documents/2024/05/30/2024-11904/notice-of-extension-of-certain-exclusions-chinas-acts-policies-and-practices-related-to-technology.

[42] "Wiley Petitions USTR to Address China's Role in Fentanyl Crisis with Section 301 Petition," Wiley, October 18, 2024, accessible here: https://www.wiley.law/pressrelease-Wiley-Petitions-USTR-to-Address-Chinas-Role-in-Fentanyl-Crisis-with-Section-301-Petition.

[43] "Section 301- China Illicit Fentanyl (Petition)," accessible here: https://ustr.gov/issue-areas/enforcement/section-301-investigations/section-301-china-illicit-fentanyl-petition.

[44] Facing Fentanyl, accessible here: https://facingfentanylnow.org/.

then argues that drug addiction and overdose deaths reduce the availability of workers in the US economy, creating a restriction on US commerce.

Fentanyl, fentanyl analogues, and methamphetamine are distributed in North America primarily by drug trafficking organizations based in Mexico, most prominently the Sinaloa Cartel and the Cartel Jalisco Nueva Generación.[45] These organizations source most of the chemical precursors used for manufacturing the drugs from chemical companies in China. Some of these chemical precursors are also illegal and the Chinese chemical manufacturers are often directly involved in the criminal activities. In recent years, the US government has begun indicting and sanctioning Chinese chemical suppliers,[46] as well as pressuring the Chinese government to crack down on the industry.[47] The petitioners argue that additional policy measures are necessary to force China to crack down more aggressively.

The petitioners first ask that USTR engage in consultations with the Chinese government through the Section 301 investigation process. In these consultations, the petitioners ask that USTR demand that China prohibit the export of all fentanyl manufacturing chemicals, materials, and equipment, and rigorously enforce the prohibitions already in place. If China does not adopt the demands, then the petition recommends that the United States impose new restrictive measures on China, including:

- Increasing tariffs on China to the equivalent of $50 billion in additional revenue collection per year (for comparison, Section 301 tariffs assessed on China since 2018 average to about $37 billion per year);
- Imposing import prohibitions on certain goods or services from Chinese entities in the chemical, biotechnology, pharmaceutical, and agricultural sectors (or in other sectors where Chinese competition negatively impacts US industry);
- Expanding outbound investment restrictions in the biotechnology, pharmaceutical, and technology sectors;
- Prohibiting Chinese-owned mobile applications from the United States;
- Eliminating the *de minimis* tariff exemption for all Chinese-originating shipments; and
- Requiring China to import $50 billion of US agricultural goods and automotive products (for comparison, the US-China Phase One Agreement committed China to importing approximately $200 billion of additional US exports in 2020 and 2021).

The petition itself asserts that none of these measures *themselves* would be useful in countering fentanyl trafficking. Instead, the petition argues the US government should treat the measures as sanctions, seeking to coerce the Chinese government into adopting stricter anti-drug trafficking policies. The petitioners state that "nothing short of significant countermeasures will incentivize the Chinese government to take meaningful action to halt the manufacture and export of illicit fentanyl, honor its commitments under international law to prohibit the trafficking of illicit fentanyl, and end the targeting of American children and families using this lethal poison."

Several of the proposed measures are redundant with policies the US government is already developing. Reducing access to *de minimis* entry and new outbound investment restrictions are already under consideration by the US government, for mostly unrelated reasons. Restrictions on certain Chinese mobile applications are also already

[45] *See*, "Fentanyl Supply Chain,' US Drug Enforcement Agency, accessible here: https://www.dea.gov/resources/fentanyl-supply-chain.

[46] *See, e.g.*, "Justice Department Announces Eight Indictments Against China-Based Chemical Manufacturing Companies and Employees," October 3, 2024, accessible here: https://www.justice.gov/opa/pr/justice-department-announces-eight-indictments-against-china-based-chemical-manufacturing.

[47] *See, e.g.*, "Biden- Harris Administration Continues Progress on Fight Against Global Illicit Drug Trafficking," November 16, 2024, accessible here: https://www.whitehouse.gov/briefing-room/statements-releases/2023/11/16/fact-sheet-biden-harris-administration-continues-progress-on-fight-against-global-illicit-drug-trafficking/.

entering force. Congress passed the Protecting Americans from Foreign Adversary Controlled Applications Act in April 2024, which targeted TikTok and empowered the president to prohibit similar applications. The Biden administration also increased tariffs on China under a separate Section 301 investigation in September 2024. The petition's proposal for temporary versions of these same policies, conditional on China changing its drug enforcement practices, may in fact be a less restrictive policy stance than the US government is currently adopting.

Section 301 investigations

Section 301 of the Trade Act of 1974 assigns authorities to USTR for investigating foreign government practices that are "unjustifiable and burdens or restricts United States commerce" and taking appropriate action to obtain remediation of the burdensome practice.[48] Since the creation of the World Trade Organization's (WTO) dispute settlement system in 1995, however, USTR has typically only used Section 301 processes to develop cases for WTO dispute settlement. Unilateral Section 301 actions resumed under the Trump administration and has continued under the Biden administration.

If the Section 301 investigation proceeds, the interagency Section 301 Committee (led by USTR) will seek public input, hold hearings, and request consultations with the Chinese government. More information on the public consultations and hearings would accompany USTR's investigation initiation notice.

Initiating the investigation would not make any commitment to the final determination or any ensuing policy actions. Section 301 investigations take up to one year to complete, meaning USTR will not reach a decision until after the next president assumes office. A negative determination would end the matter. If USTR determines that there is a trade violation, then there is an additional process for determining the appropriate remedy.

Section 301 remedies

If the Section 301 Committee reaches an affirmative determination in the Section 301 investigation, deciding on policy actions would be challenging in this context. USTR has broad discretion on how it approaches Section 301 investigations and remedies, including imposition of trade restrictions, withdrawal or suspension of trade agreement concessions, or entering binding agreements with the subject country to eliminate or compensate for the conduct in question. If the president proceeds with a trade restriction as remedy, the statute generally favors a tariff in proportion to the injury, but also allows for a broader set of import and service provision restrictions that are within the powers of the president. For illegal drug trafficking, which is already prohibited under both United States and Chinese law, there is no product on which a tariff could be applied and the commercial injury is unclear (the petitioner's suggestion for tariffs that are high enough to collect $50 billion in revenue is unrelated to the alleged injury).

USTR investigations and elections

The US government has a history of appealing to important constituencies by initiating trade investigations with timelines that cross over elections. For example, the International Trade Commission (ITC) initiated a Section 201 global safeguard investigation involving the blueberry industry, (a large agricultural industry in the swing state of Florida) shortly before the 2020 election at the request of USTR. That investigation ended the following March in a negative determination by the ITC. In September and October 2022 (a few months before the November 2022 mid-term elections), USTR considered a Section 301 investigation covering all seasonal and perishable agricultural products from Mexico (including blueberries) following complaints from farmers in Florida. The investigation ultimately did not proceed. USTR is already pursuing similar practices ahead of the 2024 election, raising current Section 301 tariffs on China in September 2024 and initiating a new Section 301 investigation of China's acts, policies, and

[48] *See*, 19 USC sections 2411-2420, accessible here: https://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title19-chapter12-subchapter3&saved=%7CKHRpdGxlOjE5IHNlY3Rpb246MjQxNCBlZGl0aW9uOnByZWxpbSk%3D%7C%7C%7C0%7Cfalse%7Cprelim&edition=prelim.

practices supporting its maritime, logistics, and shipbuilding sectors. Like any investigation that may follow from the new fentanyl petition, the shipbuilding investigation would also not be completed until after the election.

Trade Agreements

No Developments

Petitions & Investigations

No Developments