

International Trade Alert

October 19, 2016

Key Points

- OFAC's latest changes expand opportunities for U.S. persons to engage in medical research with Cuban nationals, authorize U.S. persons to obtain FDA approval of Cuba-origin pharmaceuticals, and market and sell FDA-approved Cuban-origin pharmaceuticals.
- The changes also permit foreign vessels that call on Cuban ports for trade purposes to subsequently load and unload at a U.S. port without having to wait 180 days if the items carried to Cuba would be designated as EAR99 or controlled for antiterrorism reasons if they were subject to the EAR.
- U.S. persons are now authorized to negotiate and execute contracts with Cubans for activities that require OFAC authorization, provided that such contracts are made expressly contingent on OFAC authorization or such authorization no longer being required.
- For authorized travelers to Cuba, OFAC has eliminated the monetary value limitation on items that such travelers may import into the United States with their accompanied baggage, including Cuban rum and cigars.



New Round of Cuba Sanctions Changes Expand Opportunities for Health Sector

On Monday, October 17, 2016, the U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) and the U.S. Department of Commerce's Bureau of Industry and Security (BIS) implemented amendments to the Cuban Assets Control Regulations (CACR) and Export Administration Regulations (EAR), respectively, that further ease U.S. sanctions and export controls targeting Cuba, particularly in the areas of medical research, pharmaceuticals, and trade and commerce between the United States and Cuba. These changes continue the administration's policy of easing sanctions on Cuba to support the Cuban people and follow prior regulatory changes that occurred in [January 2015](#), [September 2015](#), [January 2016](#) and [March 2016](#). This latest action follows a Presidential Policy Directive (PPD) issued on October 14, 2016, which sets out the vision, priority objectives and actions required for normalization of relations between the United States and Cuba (see [here](#)).

This latest, and perhaps final, round of changes by the Obama administration provide new opportunities for U.S. companies operating in the health sector to engage in joint research activities with Cuban

nationals and obtain FDA approval for and commercialize Cuban-origin pharmaceuticals. Additionally, the changes make it easier for U.S. companies to negotiate transactions with Cuban counterparties that require OFAC approval by allowing them to negotiate and execute “contingent contracts” that are expressly contingent on OFAC authorization or such authorization being no longer required.

Notwithstanding these latest changes, the U.S. embargo against Cuba continues to broadly restrict trade, financial services and travel between the two countries, absent general or specific authorization by OFAC and/or BIS.

A. Overview of Recent Amendments

Health-related Activities

Several of the regulatory amendments implemented on October 17, 2016, expand opportunities for U.S. persons to engage in health-related activities with Cuban nationals, particularly in the areas of medical research and pharmaceuticals.

- **Joint Medical Research:** OFAC issued a new general license that authorizes U.S. persons to “engage in all transactions incident to joint medical research projects with Cuban nationals,” including both commercial and noncommercial medical research. Notably, this general license does not authorize U.S. persons to establish a business or physical presence in Cuba or hire Cuban nationals as part of their research activities. These activities still require a specific license from OFAC. Travelers to Cuba for joint medical research projects must also continue to ensure that their activities in Cuba are consistent with a full schedule of professional research activities.
- **Cuban-Origin Pharmaceuticals:** OFAC issued a general license authorizing U.S. persons to engage in “all transactions incident to obtaining approval from the FDA of Cuban-origin pharmaceuticals, including discovery and development, pre-clinical research, clinical research, regulatory review, regulatory approval and licensing, regulatory post-market activities, and the importation into the U.S. of Cuban-origin pharmaceuticals.” In addition, OFAC now permits the import, marketing, sale and distribution in the United States of FDA-approved Cuban-origin pharmaceuticals.
- **Cuban Bank Accounts:** The regulatory amendments authorize U.S. persons engaged in the above-referenced activities to open, maintain and close bank accounts at Cuban financial institutions, provided the accounts are used solely for authorized activities.

Trade and Commerce with Cuba

The regulatory amendments also aim to expand trade and commerce between the United States and Cuba through changes that facilitate authorized trade activities.

- **Exception to 180-Day Rule for Certain Foreign Vessels:** Under current Cuba sanctions, foreign vessels that call on Cuban ports for trade purposes are generally prohibited from entering U.S. ports for loading and unloading for 180 days from the date they depart from Cuba, unless authorized by OFAC or an exception applies. OFAC created a new exception to this rule for foreign vessels that have carried from a third country to Cuba items that would be designated as EAR99 or controlled on the Commerce Control List (CCL) for antiterrorism reasons only if subject to the EAR.

- **Transactions Incident to Export-related Transactions:** Though a general license, OFAC authorizes transactions “ordinarily incident” to certain export- and re-export-related transactions authorized by BIS. Previously, with respect to re-export transactions, this general license only authorized the re-exportation of 100 percent U.S.-origin items from a third country to Cuba. The new amendments implemented on October 17 remove the reference to “100% U.S.-origin items” to minimize the need for a specific license from OFAC to export or re-export U.S.-origin items to Cuba, which have been authorized by BIS. The amendments also permit U.S. persons to import into the United States items from a third country for exportation to Cuba pursuant to authorization by BIS. However, because of statutory restrictions, U.S.-owned or -controlled companies in third countries remain generally prohibited from exporting to Cuba commodities produced in a country other than the United States or Cuba, subject to certain limited exceptions.
- **Export Financing:** OFAC has made a technical correction to the regulations to clarify that only “agricultural commodities,” such as food, feed, livestock, fibers, seeds and fertilizers, are subject to the limitations on payment and financing terms required under the Trade Sanctions Reform and Export Enhancement Act of 2000. Previously, the financing limitations applied to “agricultural items,” a term that encompasses non-agricultural commodities such as pesticides and agricultural equipment.
- **Imports of Previously Exported Items:** OFAC issued a new general license to authorize items previously exported or re-exported to Cuba to be imported into the United States or a third country. This license also permits U.S. persons to service and repair these items. However, the export or re-export of serviced, repaired, or replacement items to Cuba still requires authorization by OFAC and/or BIS.
- **Aircraft Cargo:** BIS amended license exception Aircraft, Vessels and Spacecraft to generally allow air cargo to transit Cuba, provided it is not removed from the aircraft or vessel for use in Cuba. This amendment conforms the rule for aircraft with that available for vessels on temporary sojourn to Cuba.
- **Direct Sales to Cuban Individuals:** BIS expanded license exception Support for the Cuban People to permit the sale of items (including online sales) directly to individuals in Cuba for their personal use or their immediate family’s personal use, excluding Members of the Council of Ministers, flag officers of the Revolutionary Armed Forces and Members of the Politburo.

Contingent Contracts

OFAC issued a new general license that allows U.S. persons to negotiate and execute “contingent contracts” for activities that require OFAC authorization. Such contracts must be made contingent on OFAC authorization of the underlying activity or on the elimination of an authorization requirement (e.g., if Congress acts to lift the embargo in the future). In addition, if the activity implicates another federal agency’s licensing requirements (e.g., a BIS export license), the contract would also need to be made contingent upon prior authorization of that agency or removal of those licensing requirements.

Travel

The regulatory amendments also affect travel-related transactions. Most notably, the amendments eliminate the monetary value limitation on items that authorized travelers to Cuba may import into the United States with their accompanied baggage. Prior to the amendment, authorized travelers subject to U.S. jurisdiction could only import Cuban merchandise into the United States with a value of \$400 or less, with a \$100 limit on alcohol or tobacco products. In conjunction with this change, OFAC also eliminated the prohibition on foreign travelers importing Cuban alcohol or tobacco products into the United States, provided the products are in their accompanied baggage, not in commercial quantities, and not imported for resale.

Separately, OFAC also expanded the professional research and professional meetings general license by eliminating the condition that such meetings and conference “not be for the promotion of tourism in Cuba.”

Cuban Infrastructure Development

OFAC now authorizes U.S. persons to provide Cuba or Cuban nationals with services related to developing, repairing, maintaining and enhancing Cuban infrastructure, provided such activities are consistent with the export or re-export licensing policy of the Department of Commerce. OFAC interprets “infrastructure” to mean systems and assets used to provide the Cuban people with goods and services produced by the public transportation, water management, waste management, non-nuclear electricity generation and electricity distribution sectors, as well as hospitals, public housing, and primary and secondary schools. In addition, this authorization permits projects related to environmental protection.

Grants, Scholarships and Awards

OFAC expanded an existing general license for humanitarian projects to permit U.S. persons to provide “grants, scholarships and awards” to Cuban nationals in the areas of educational activities, humanitarian projects, scientific research and religious activities. OFAC has issued informal guidance that states that such grants, scholarships or awards may be provided to a “Cuban state-owned entity or any other entity in which Cuba or a Cuban national otherwise has an interest” provided they are used for educational activities, humanitarian projects, scientific research or religious activities. However, the federal government continues to remain statutorily prohibited from providing grants to the Cuban government.

Civil Aviation

OFAC implemented a new general license authorizing U.S. persons to provide Cuban nationals, wherever located, services related to civil aviation safety and the safe operation of commercial aircraft.

B. Presidential Directive

On October 14, 2016, President Obama issued a PPD on the normalization of relations between the United States and Cuba. The directive reiterates the administration’s efforts to reestablish diplomatic relations with Cuba and bring to an “irreversible” end “an outdated policy that had failed to advance U.S. interests and support reform and a better life for the Cuban people on the island over several decades.”

Notably, the PPD charts six U.S. medium-term objectives for the normalization of relations with Cuba, including:

- Continued government-to-government cooperation in key areas of mutual interest, including agriculture, the economy and small businesses, transportation, science and technology, environment, climate, health, law enforcement, migration, national security, disaster preparedness and response, and counterterrorism.
- Encouragement of people-to-people linkages through publicly and privately sponsored exchanges involving educational, cultural, business, science, environment, technology and sports activities.
- Expanded commerce with Cuba and continuance of policies that enable authorized U.S. private sector engagement with Cuba's emerging private sector and with state-owned enterprises that provide goods and services to the Cuban people.
- Support for Cuban economic reform efforts, and commencement of dialogue with Congress on economic exchanges and a potential bilateral commercial agreement with Cuba, if and when the embargo is lifted.
- Providing support and encouragement in furtherance of universal human rights, fundamental freedoms and democratic values in Cuba.
- Expanded dialogue with Cuba in multilateral organizations such as the World Trade Organization and the World Customs Organization.

C. Significance of Changes

The latest amendments further advance the Obama administration's efforts to normalize relations with Cuba in strategic areas such as health, trade and commerce, and people-to-people contact. Coupled with the Presidential Policy Directive on the normalization of relations with Cuba, this latest action helps to cement the Obama administration's legacy with respect to Cuban relations and its efforts to permanently reverse long-standing foreign policy with the island nation.

However, the comprehensive U.S. embargo against Cuba remains codified in statute and can only be reversed by Congressional action. Specific limitations that are codified in statute, such as provisions restricting U.S. financial institutions' financing of U.S. agricultural commodity exports to Cuba, will also remain in effect absent legislative action. We will continue to monitor developments as they unfold, and we encourage clients to contact us to learn more about how these changes impact specific business operations and opportunities.

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