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Census Wants to Keep Option 4 for Current, New Users

The Census Bureau has drafted a proposal for criteria that would allow existing users of post-departure Option 4 for filing export documentation to retain their eligibility and to reopen the program for new users. Census officials plan to present their proposal in the coming weeks to Customs and Border Protection (CBP), whose support for the plan is needed before it can be implemented. Census also wants to abandon an earlier proposed change to the Foreign Trade Regulations (FTR), which would have limited Option 4 to certain bulk commodities.

The criteria for eligibility for existing Option 4 users, who will have to reapply for participation, and new applicants will be based mainly on their compliance with the Automated Export System (AES), Dale Kelly, assistant director of Census' data collection division, told the Bureau of Industry and Security's (BIS) Regulations and Procedures Technical Advisory Committee (RAPTAC) Sept. 13. Among the issues that will be considered are a firm's compliance rate, including fatal errors, its responsiveness to Census requests for information, how often it exports and what products it exports, she noted.

"One of the issues CBP has had all along is that we're allowing goods to go out of the country and there's no information being filed," Kelly pointed out. She acknowledged that the criteria for eligibility before a moratorium was placed on new participants in 2003 might not have been strong enough. "So what we've been trying to do is come up with some stronger criteria; some things we can look at now that we have more automated information," she said.

"None of this is written in stone and it is certainly something that has to be agreed upon by BIS, as well as CBP and, of course, State has to concur on our regulations," she cautioned. RAPTAC members urged Census to publish a notice, even before a final rule is published, to alert current Option 4 users that the program will remain available and won't be based on commodities. They noted that many current users are in the process of revising their export programs in anticipation of losing the post-departure reporting option and a notice from Census would prevent that unnecessary effort (see **WTTL**, June 20, page 1).

USTR Paper on Medicines in TPP Draws Mixed Response

A U.S. Trade Representative (USTR) white paper and initiative, called "Trade Enhancing Access to Medicines" (TEAM), aimed at protecting drug research and patents as part of the Trans-Pacific Partnership (TPP) negotiations, met with instant criticism from nongovernment



organizations (NGOs) and a “wait and see” attitude from the pharmaceutical industry. Released during TPP talks in Chicago Sept. 12, TEAM is “designed to deploy the tools of trade policy to promote trade in, and reduce obstacles to, access to both innovative and generic medicines, while supporting the innovation and intellectual property protection,” the white paper said.

The white paper was issued during the eighth round of TPP negotiations, which concluded Sept. 15 after “10 days of intensive and fruitful talks,” according to U.S. officials. They said negotiations are “moving toward closure” on customs, technical barriers to trade, telecommunications, government procurement, small- and medium-sized enterprises, regulatory coherence, competitiveness and development. The officials reported that progress was also made on more complex subjects such as intellectual property and investment.

U.S. drug firms are closely watching the TPP talks, Mark Grayson, spokesman for PhRMA, the pharmaceutical industry trade group, told WTTL. “Industry is certainly wondering how that will work, and how countries will implement it. We can’t say it’s good or bad or indifferent.”

At issue among NGOs, Congress and the drug industry is protection for proprietary regulatory data, which is not mentioned in the white paper specifically. Drugmakers want 12 years of data protection for biologics. In a Sept. 12 letter to USTR Ron Kirk, 37 senators, led by Sens. John Kerry (D-Mass.) and Orrin Hatch (R-Utah), said a 12-year term “best supports the Congress’ goals of maintaining the nation’s competitiveness as the leading innovator of biologics products, increasing the number of high-value jobs, and improving access to safe and affordable medicines by creating a clear pathway for the regulatory approval of biosimilar drugs.”

One sticking point is the “TPP access window”, which the white paper says would “establish a pathway for generics to enter those markets as quickly as possible by conditioning obligations to apply certain pharmaceutical-specific intellectual property protections on the requirement that innovators bring medicines to TPP markets within an agreed window of time.”

Knowledge Ecology International (KEI), a vocal critic of the U.S. negotiations on drug patents, posted a blog saying: “One has to read between the lines, and guess what the White House is trying to say (or avoid saying plainly). It appears as though USTR will demand TPPA partners agree to several years of exclusive rights in regulatory test data for new medicines, including biologic drugs” (see WTTL, March 28, page 1). Doctors Without Borders, also known as Medecins sans Frontiers (MSF), also complained about the paper. MSF sees “the U.S. and the pharmaceutical industry looking to impose some of the most stringent patent protections we’ve seen to date, significantly delaying introduction of generic medicines in the countries that sign up to the TPP and creating a fundamental contradiction between U.S. trade policy and U.S. commitments to global health,” said Sophie Delaunay, MSF-USA executive director.

Industry Calls for Changes to Specially Designed Definition

The two-part definition for the term “specially designed” that the Bureau of Industry and Security (BIS) proposed in July has caused “quite a bit of confusion” and “difficulty in understanding the proposal,” according to Maggie Hershey, senior policy director with Semiconductor Equipment and Materials International (SEMI), the industry trade association. SEMI has filed comments with BIS calling for several changes to the proposed definition, including issuing a single definition based on the “peculiarly responsible” concept that would apply to end products as well as parts, components and accessories, Hershey told the BIS Regulations and Procedures Technical Advisory Committee (RAPTAC) Sept. 13.

The various exceptions and notes to the definition for parts and components make it “a very complicated proposal,” Hershey told RAPTAC. Even industry experts who participated in a SEMI working group that reviewed the proposal found it difficult to interpret, she noted. “I had to read it many times to understand what it was saying,” she added. “To someone who is a new exporter or a small exporter, I think it would be very challenging to figure out and apply,”

she said. RAPTAC members agreed with her complaints about the proposed definition. “This would get an ‘F’ if it went through my old English teacher,” one committee member complained. “Double negatives, run-on sentences, reuse of words, reuse of phrases, parentheticals on top of parentheticals. It’s just bad,” he continued.

Another member noted that the complexity of the definition would require exporters to get legal advice to make sure they were interpreting it correctly. This would hurt exporters of small shipments, the value of which might be less than the cost of a lawyer, she said. Other members noted that different firms in the U.S. and abroad treat parts, components and accessories differently with some treating them as controlled and others as uncontrolled.

In response to a SEMI proposal for revising the language of the definition into plain English, RAPTAC members said they would try to draft a plain English version of the proposal and submit it to BIS. In addition to having one definition for end-items and parts and components, SEMI is urging BIS to state explicitly in the final rule that the new definition would not change the status of an item that was the subject previously of a Commodity Classification ruling that said it was not controlled. It wants the exclusion for single unassembled parts, such as nuts and bolts, to apply to “simple assemblies” containing two or three parts.

SEMI urged BIS to drop the phrase “form, fit and function” and focus only on function as a criterion for control. Another suggestion would add an exclusion from the definition for parts that only facilitate the use of an item but don’t change its fundamental character. Finally, it urged BIS to provide an 180-day grace period for compliance with the new rules to give firms time to make the significant changes that will be required to export compliance programs.

Agencies Plan Rollout of List Changes This Year

BIS and State officials plan to propose changes in at least five categories on the U.S. Munitions List (USML) and the transfer of many items in those categories to the Commerce Control List (CCL) in the next three and a half months, according to Kevin Kurland, director of the BIS office of technology evaluation. “It is our expectation that rebuilt categories VIII [aircraft] and VII [military vehicles], starting with VIII, will be on the street next month, no later than that, followed by VI [vessels of war] and XIX [new category for engines] and XV [spacecraft],” Kurland told the BIS RAPTAC Sept. 13.

USML Category XIX, which is now a blank “Reserved” category will become populated with engines from categories VI, VII and VIII. At the same time, BIS will create a new Export Control Classification Number (ECCN) in the 600 series, ECCN xx619, for USML engines moved to the CCL.

Kurland noted that of the 12,000 items controlled under USML Category VII, about 91% would move to the CCL under the coming proposal. Of those 11,000 items, 50% will be immediately eligible for License Exception Strategic Trade Authorization (STA); 35% would require a license as end-items but could be eligible for STA after a one-time review; and 15% would be automatically eligible for export as “No License Required” except to T-Group countries and military end-uses in China. He said State’s Directorate of Defense Trade Controls (DDTC) issued about 2,000 licenses for parts and components alone under this category in 2010.

The proposed changes to Category XV for spacecraft will become part of a report the Defense Department is required to file with Congress on the impact current restrictions on satellite exports have on national security and U.S. competitiveness. Legislation would be needed to allow State to transfer control of satellite exports to BIS. “What we’ve agreed to do when we rebuild Cat XV is to submit a final [Section] 1248 report back to the committees,” Kurland reported. “Certainly, that will influence the corresponding 600 series,” he added. “We are making adjustments to that report so that it’s consistent with the outcome of those two sets of lists,” he said. “Hopefully, it [the report] satisfies those who are interested in moving

legislation that would give the president the authority back to determine the jurisdiction of satellite items as he deems fit consistent with national security,” Kurland noted. Meanwhile, no agreement has been reached yet with congressional committees on how they want to handle required notifications from State under Section 38(f) of the Arms Export Control Act on proposed transfers from the USML to the CCL, Kurland reported.

“I know there has been a lot of discussion at senior levels; there have been discussions at working levels,” he noted. “I know we are not going to be negotiating with them on an item-by-item level,” he added. “It’s a process that the White House is taking the lead on, working with the State Department to find an accommodation that is acceptable to them and allows us to move forward as expeditiously as possible,” Kurland told RAPTAC.

* * * **BRIEFS** * * *

FCPA: Bridgestone Corp. Sept. 15 agreed to plead guilty in Houston U.S. District Court and pay \$28 million criminal fine for, among other charges, conspiring to violate FCPA by making corrupt payments to foreign government officials in Latin America related to sale of marine hose and other industrial products. Misao Hioki, its former general manager for international engineered products, also had pleaded guilty and was sentenced to two years in prison in 2008 for his role in FCPA conspiracy.

EXPORT ENFORCEMENT: Nadeem Akhtar of Silver Spring, Md., Pakistani national and lawful permanent resident of U.S., pleaded guilty Sept. 9 in Baltimore U.S. District Court to conspiring to commit export violations and to defraud U.S. in connection with scheme to illegally export nuclear-related materials, including radiation detection devices, resins for coolant water purification, calibration and switching equipment, attenuators and surface refinishing abrasives, to restricted entities in Pakistan (see **WTTL**, March 14, page 6). Sentencing set for Jan. 6, 2012.

IMPORTS: ITC Sept. 12 in its updated report *The Economic Effects of Significant U.S. Import Restraints* estimates U.S. economic welfare, as defined by total public and private consumption, would increase by about \$2.6 billion annually by 2015 if U.S. unilaterally ended all significant import restraints. Exports would expand by \$9.0 billion and imports by \$11.5 billion. This includes removing import barriers in sugar, ethanol, canned tuna, dairy products, tobacco, textiles and apparel, and other high-tariff manufacturing sectors, ITC says.

IRAN: State in Federal Register Sept. 14 lifted sanctions on Israeli conglomerate, Ofer Brothers, under CISADA but added two of its entities: Allvale Maritime Inc. and Société Anonyme Monégasque D'Administration Maritime Et Aérienne (SAMAMA), clarifying notice published in May (see **WTTL**, May 30, page 4). “The complex nature of the conglomerate’s business structure necessitated that we take the time to look closely at these companies in order to ensure that we were identifying the precise legal names of the entities directly responsible for the sanctionable transaction,” State spokesperson said.

SULFANILIC ACID: ITC Sept. 14 made “sunset” review determination that lifting countervailing duty order on sulfanilic acid from India and antidumping orders on imports from China and India would likely lead to renewed injury to U.S. industry. Vote was 6-0.

SOFTWOOD LUMBER: USTR in Sept. 15 Federal Register is inviting public comments on two-year extension of U.S.-Canada Softwood Lumber Agreement (SLA). SLA is currently scheduled to expire on Oct. 12, 2013 (see **WTTL**, Aug. 15, page 4).

BUY AMERICA: Canada asked for talks Sept. 14 with U.S. to discuss Buy America provisions in President Obama’s jobs proposal. While U.S. and Canadian federal governments, Canadian provinces and 37 U.S. states are covered by WTO Government Procurement Agreement, Ottawa is concerned that funds under legislation would go to lower-level municipalities, counties and local school boards that aren’t covered and might bar bids from Canadian suppliers.

SANCTIONS: Rep. Kevin Brady (R-Texas), who chairs House Ways and Means Committee’s trade subcommittee, urged adoption of “smarter sanctions policy” in Sept. 13 speech to USA-Engage. Brady said he wants Ways and Means to assert its jurisdiction more strongly over restrictions on U.S. imports in sanctions legislation. He offered five factors that should be considered before enactment of sanctions: (1) consistency with WTO and other trade agreement obligations, (2) presidential waiver discretion, (3) inclusion of “sunset” provision, (4) required annual presidential report on effectiveness of sanctions, and (5) impact on citizens of targeted country.