

## COVID-19 Supply Chain and Trade Update

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April 9, 2020

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### New Presidential Memorandums Target Private Manufacturing to Address Shortages in Medical Equipment

Three new Presidential Memoranda (PMs) addressing the COVID-19 pandemic were released by President Trump on April 2nd and 3rd. These PMs were issued pursuant to the Defense Production Act of 1950 (DPA), which grants the federal government authority to take extraordinary measures to facilitate the production of goods and services necessary for national defense, defined broadly to include "emergency preparedness activities."

Reports have indicated certain near-term responses to the below PMs. According to these reports, General Electric Healthcare has scaled up its production of ventilators; a shipment of face masks manufactured by 3M Company destined for Canada was temporarily halted by the federal government; and the Federal Emergency Management Agency (FEMA) has seized shipments of personal protective equipment (PPE) as part of its prioritization of deliveries of PPE to COVID-19 hotspots.

#### *Granting Authority to Acquire N-95 Respirators Made by 3M Company*

On April 2, 2020, President Trump [issued a PM](#) pursuant to the DPA authorizing the Secretary of Homeland Security through the Administrator of the Federal Emergency Management Agency "to acquire, from any appropriate subsidiary or affiliate of 3M Company, the number of N-95 respirators that the Administrator determines to be appropriate."

#### *Facilitating Ventilator Production*

On the same day, a [second PM](#) issued pursuant to the DPA granted the Secretary of Homeland Security the authority to facilitate the supply of materials for the production of ventilators from General Electric Company; Hill-Rom Holdings, Inc.; Medtronic Public Limited Company; ResMed Inc.; Royal Philips N.V.; and Vyair Medical, Inc. The order applies to those companies' subsidiaries and affiliates as well.

#### *Allocating Scarce Medical Resources to Domestic Use*

On April 3, 2020, President Trump issued a PM pursuant to the DPA which authorizes the Secretary of Homeland Security to take any actions available under the DPA allocate scarce or threatened medical resources to domestic use, including personal protective equipment (PPE) such as respirators, surgical masks, and gloves. These are resources used in responding to the spread of COVID-19 that would become scarce if there is accumulation in excess of the reasonable consumption, or for the purpose of resale at prices in excess of prevailing market prices. The PM also states that "... it is the policy of the United States to prevent domestic brokers, distributors, and other intermediaries from diverting such material overseas." More information on the items covered by the PM is [available here](#).

## CBP Launches New Webpage to Track COVID-19 Updates and Announcements; Forms New Team to Facilitate the Import of Medical Supplies and PPE

On April 2, 2020, Customs and Border Protection (CBP) launched a new [CBP COVID-19 Updates and Announcements](#) webpage to streamline communications and support the trade community during the pandemic. The webpage collects updated information related to COVID-19, including Federal Register Notices, Cargo Systems Messaging Service (CSMS) communications, and updates and announcements regarding trade programs and cargo security, as well as links to other government agencies' COVID-19 response websites. The page will be updated regularly to reflect the most current information available.

CBP has also established the COVID-19 Cargo Resolution Team (CCRT) in order to coordinate inquiries regarding the import of medical supplies and personal protective equipment (PPE). The multidisciplinary team will triage incoming inquiries, coordinate with affected ports, and can respond directly to members of the trade community. CCRT can be contacted at [COVID19\\_RELIEF\\_IMPORTS@cbp.dhs.gov](mailto:COVID19_RELIEF_IMPORTS@cbp.dhs.gov).

CCRT is currently accepting messages at the above email address related to (1) facilitation requests from other government agencies and private industry; and (2) general inquiries regarding the import of medical instruments. To assist the facilitation of requests, CCRT asks for:

- Shipment information: manifest or air waybill numbers, tracking numbers, entry numbers, mode of transport information
- Conveyance information: carrier name, mode of transportation, flight number, vessel/voyage number, port of arrival, port of entry
- Cargo description: complete description of the goods being shipped
- Country information: country of manufacture, country of export
- Parties involved: names and locations of manufacturers, shippers, importers, and consignees

## New FDA Guidance on Importing PPE

On April 4, 2020, the Food and Drug Administration (FDA) provided industry with [additional guidance](#) regarding the submission of entry information for personal protective equipment (PPE) and certain other devices related to COVID-19. This updates [earlier guidance](#) released on March 26, 2020 via CBP's Cargo Systems Messaging Services (CSMS). The updated guidance addresses three main classifications of PPE:

### 1. *PPE Not Regulated by the FDA*

PPE that is intended for general purpose or industrial use (i.e., products that are not intended for use to prevent disease or illness) are not regulated by the FDA and entry information should be transmitted to CBP, not the FDA. Importers should use an appropriate HTS code with no FD Flag; or use an appropriate HTS code with an FD1 flag and do a 'disclaim' for FDA.

### 2. *PPE Covered by an Emergency Use Authorization (EUA)*

Products authorized for emergency use pursuant to an Emergency Use Authorization (EUA) are regulated by the FDA and entry information should be submitted to the FDA. Importers should transmit an Intended Use Code of "940.000: Compassionate Use/Emergency Use Device." However, the FDA has reduced the amount of information necessary for review. Currently, EUAs apply to:

- a. Diagnostic tests identified as 83QKP, 83QKO, and 83QJR;
- b. Masks or respirators identified as 80NZJ; and

c. Ventilators as identified by the [Ventilator EUA](#).

Importers should note that the earlier CBP message incorrectly identified the diagnostic test code as QPK. More guidance on the EUAs is available [here](#).

3. *PPE Regulated by the FDA and Not Authorized by an EUA*

For products that are regulated by the FDA but are not subject to a EUA, importers should submit entry information to the FDA. Certain products used in the fight against the global pandemic are subject to an enforcement discretion policy published as guidance even though they are not subject to a EUA. Importers of these products should use intended use code “081.006: Enforcement Discretion per Final Guidance” and an appropriate FDA product code. The items currently in this category are:

- a. [Clinical Electronic Thermometers](#)
- b. [Gowns, Other Apparel, and Gloves](#)
- c. [Sterilizers, Disinfectant Devices and Air Purifiers](#)
- d. [Face Masks and Respirators](#)
- e. [Non-Invasive Remote Monitoring Devices](#)
- f. [Ventilators and Accessories and Other Respiratory Devices](#)

A [full list of all guidance documents related to COVID-19](#) is also available on FDA’s website. Questions regarding this guidance can be submitted to FDA at [COVID19FDAIMPORTINQUIRIES@fda.hhs.gov](mailto:COVID19FDAIMPORTINQUIRIES@fda.hhs.gov) or 301-796-0356.

## World Trade Organization Tracks New COVID-19 Trade Related Measures

The World Trade Organization (WTO) has formed a taskforce in response to the COVID-19 pandemic and is tracking the latest disruptions to international trade on their [new webpage](#). The webpage includes FAQs, updates from WTO members, “real-time” trade barometers, and global business/civil society responses to COVID-19. WTO is also tracking countries that have imposed trade related measures in response to COVID-19. This list was last updated on April 6, 2020 at the time of publication. While the list is not exhaustive, it indicates that the majority of trade measures involve restrictions on the export of medical supplies, along with a growing number of restrictions on food exports.

The WTO reports that the European Union, Colombia, Costa Rica, Thailand, Indonesia, Pakistan, Malaysia, Morocco, Ecuador, Ukraine, the United Kingdom, Albania, Algeria, and Australia have all banned the export of certain personal protective and medical equipment. The Kyrgyz Republic, Colombia, Thailand, El Salvador, Honduras, and North Macedonia have gone even further and have prohibited the export of certain essential food products. Indonesia, Mauritius, the Russian Federation, and Kazakhstan have all placed restrictions on the import of live animals from certain countries.

However, other countries are liberalizing their import regimes. Canada, New Zealand, Panama, India, Colombia, Paraguay, Uruguay, the Philippines, and Brazil have temporarily eliminated tariffs on certain personal protective equipment.

For more information, see the [WTO Trade and Trade Related Measures List](#).

## CBP Reverses Course on Payment Deferrals

On March 27, 2020 CBP released [message 42179313](#) via Cargo Systems Messaging Service (CSMS), which provided additional guidance regarding previous messages related to entry summary payments impacted by COVID-19 and to confirm that payments deferral requests are no longer accepted.

Earlier, on March 20, 2020, CBP released message [42097586](#), which allowed importers to request an extension for the payment of estimated duties, taxes and fees. However, on March 26, 2020, CBP issued CSMS message [42161666](#), which notified the trade community that CBP was no longer accepting requests for additional days for payment.

The latest messages clarifies that CSMS message [42161666](#) applies to all parties who have submitted a request to CBP in writing for

additional days for payments from March 20 – 26, regardless to whether a response was received by CBP. All payments that should have been made prior to March 26th but were deferred due to CBP's earlier message released on March 20th are now due as of March 27th. Any future payments due according to standard procedures, and no deferral requests will be accepted.

## CBP Revokes Withhold Release Order (WRO) on Disposable Rubber Gloves

On March 24, 2020, CBP removed the Withhold Release Order (WRO) for disposable rubber gloves imported by WRP Asia Pacific Sdn. Bhd. (Asia Pacific). All rubber gloves manufactured by Asia Pacific after March 16, 2020 will be admissible at all U.S. ports of entry. Asia Pacific's gloves were initially barred from entry into the U.S. by WRO in September 2019 due to the presence of forced labor conditions. CBP announced that they have lifted the WRO as Asia Pacific has now addressed their concerns over working conditions and adheres to the International Labor Organization's labor standards. For more information, see the CBP [press statement](#).

While the current global pandemic is not cited as a factor for lifting the WRO, CBP Executive Assistant Commissioner for the Office of Trade Brenda Smith stated that "[w]e are very pleased that this effort successfully mitigated a significant supply chain risk and resulted in better working conditions and more compliant trade." More information on WROs is available [here](#).

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