



FedEx Regulatory Alerts & Updates

Regulatory Alert: Changes to FEMA'S U.S. PPE Export Review Process

August 10, 2020

Background

The novel coronavirus (COVID-19) pandemic has resulted in a scarcity of personal protective equipment (PPE) in the U.S. A Presidential Memorandum was issued on April 3, 2020 announcing an export review of shipments of PPE by the Federal Emergency Management Agency (FEMA).

FEMA published a "Notification of Exemptions" in the Federal Register on April 21, 2020 addressing ten categories of covered materials excluded from the export review. Also included in FEMA's Notification were details regarding the Letter of Attestation (LOA) to be submitted via CBP's Document Imaging System for certain exemptions. This LOA is used by FEMA to certify the purpose of the shipment of covered materials.

Here are the ten specific categories of covered materials that FEMA has determined to be exempt from the PPE export review:

1. Shipments to U.S. Commonwealths and Territories, Including Guam, American Samoa, Puerto Rico, U.S. Virgin Islands, and the Commonwealth of the Northern Mariana Islands (Including Minor Outlying Islands)
2. Exports of Covered Materials by Non-profit or Non-governmental Organizations that are Solely for Donation to Foreign Charities or Governments for Free Distribution (Not Sale) at their Destination(s) (LOA required)
3. Intracompany Transfers of Covered Materials by U.S. Companies from Domestic Facilities to Company-owned or Affiliated Foreign Facilities (LOA required)
4. Shipments of Covered Materials that are Exported Solely for Assembly in Medical Kits and Diagnostic Testing Kits Destined for U.S. Sale and Delivery (LOA required)
5. Sealed, Sterile Medical Kits and Diagnostic Testing Kits Where Only a Portion of the Kit is Made Up of One or More Covered Materials That Cannot be Easily Removed Without Damaging the Kits
6. Declared Diplomatic Shipments from Foreign Embassies and Consulates to their Home Countries
7. Shipments to Overseas US Military Addresses, Foreign Service Posts (e.g., Diplomatic Post Offices), and Embassies

8. In-Transit Merchandise: Shipments in Transit through the U.S. with a Foreign Shipper and Consignee, Including Shipments Temporarily Entered into a Warehouse or Temporarily Admitted to a Foreign Trade Zone (LOA required)
9. Shipments for Which the Final Destination is Canada or Mexico (LOA required)
10. Shipments by or on behalf of the U.S. Federal Government, including its Military

This export review process was set to expire on August 10, 2020.

What's New?

On August 10, 2020, FEMA announced that it is extending the validity of this temporary final rule as part of its response to the COVID-19 pandemic. The expiration date of this export review process is now December 31, 2020.

FEMA also declared that the list of products covered by the temporary final rule has been modified. The list of goods impacted by this restriction now includes:

- Surgical N95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates
- PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials
- PPE nitrile gloves, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such nitrile gloves intended for the same purposes
- Level 3 and 4 Surgical Gowns and Surgical Isolation Gowns that meet all of the requirements in ANSI/AAMI PB70 and ASTM F2407-06 and are classified by Surgical Gown Barrier Performance based on AAMI PB70

Q&A

Q1: What criteria does FEMA use to make the decision on allowing a specific PPE shipment to be exported or not?

A1: FEMA considers the "totality of circumstances" in making a decision, including:

1. The need to ensure that scarce or threatened items are appropriately allocated for domestic use
2. Minimization of disruption to the supply chain, both domestically and abroad;
3. The circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns
4. The quantity and quality of the materials
5. Humanitarian considerations
6. International relations and diplomatic considerations

Q2: If FEMA decides NOT to allow a given shipment of PPE articles to be exported, what actions are taken?

A2: FEMA may review shipments of covered materials and, subject to certain exemptions, determine whether to (1) purchase some or all the shipment through a Defense Protection Act priority-rated order or (2) return some or all the shipment for domestic use.

Q3: What information needs to be included in the LOA?

A3: The LOA should contain the following information:

1. A description of which exemption(s) the exporter is claiming
2. Details regarding the shipment that are sufficient for the CBP and FEMA officials to determine whether the shipment falls under the claimed exemption(s)
3. A statement that the provided information is true and accurate to the best of the exporter's knowledge, and that the exporter is aware that false information is subject to prosecution under the DPA, as outlined in the allocation order

Exporters who have concerns about how to file this letter of attestation for their FedEx Express export shipment should reference Q&A # 7 below.

Q4: What if customers fail to include the LOA in their shipment paperwork?

A4: FEMA has deemed the LOA as a required document for the specific exclusion. Failure to include it could lead to the shipment being held for review purposes.

Q5: Are all of the ten exemptions in place for the duration of this PPE export review action?

A5: FEMA may waive any of the exemptions at any time and fully review shipments of covered materials under 44 CFR 328.102(b) if it is determined that doing so is necessary or appropriate to promote the national defense.

Q6: Are any export shipments exempted based on a low value or the number of items in the shipment?

A6: There is not an exemption based on shipment value or number of items in a shipment. Low value export shipments can be reviewed like any other export shipment under this process.

Q7: How can I submit my LOA to CBP for my FedEx Express export shipment?

A7: In order for CBP to review all export documentation prior to the physical export of the shipment, U.S. export shippers should include a copy of the LOA with the commercial invoice and other shipment documentation. Another option, if the U.S. exporter self-files their EEI data into the Automated Export System (AES), the LOA can be included with the submission directly in the Document Imaging System (DIS).

As CBP noted in CSMS #42439611, when submitting to DIS, filers have the following options to transmit:

- Electronically through secure web services, file transfer protocol, or messaging queue
- By email to docs@cbp.dhs.gov

References:

August 10 FEMA temporary final rule extending and modifying the PPE export review process

<https://www.govinfo.gov/content/pkg/FR-2020-08-10/pdf/2020-17467.pdf>

April 21 FEMA Federal Register "Notification of Exemptions"

<https://www.govinfo.gov/content/pkg/FR-2020-04-21/pdf/2020-08542.pdf>

U.S. Customs and Border Protection CSMS #42439611

[https://content.govdelivery.com/bulletins/gd/USDHSCBP-28793bb?wgt_ref=USDHSCBP_WIDGET_2?utm_source=csms.cbp.gov&utm_medium=csms.cbp.gov&utm_term=undefined&utm_content=undefined&utm_campaign=\(not%20set\)&gclid=undefined&dclid=undefined&GAID=1485270042.1545403577](https://content.govdelivery.com/bulletins/gd/USDHSCBP-28793bb?wgt_ref=USDHSCBP_WIDGET_2?utm_source=csms.cbp.gov&utm_medium=csms.cbp.gov&utm_term=undefined&utm_content=undefined&utm_campaign=(not%20set)&gclid=undefined&dclid=undefined&GAID=1485270042.1545403577)