



# FedEx Regulatory Alerts & Updates

## **Regulatory Alert Update: Extension of FEMA U.S. PPE Export Review Process**

January 12, 2021

### **Background**

The U.S. Federal Emergency Management Agency's (FEMA) Temporary Final Rule (TFR) on the export of scarce personal protective equipment (PPE) went into effect on April 10, 2020, and was subsequently extended on Aug. 10, 2020, with some modification.

This TFR was due to expire Dec. 31, 2020.

### **What has changed?**

FEMA published an updated rule in the Federal Register on Dec. 31, 2020 to help ensure that critical health and medical resources remain accessible to the American public during the COVID-19 pandemic.

This rule modifies an allocation order of health and medical resources that was published in the spring and updated in the summer to reflect changing circumstances of supply and demand. The rule has modified the list of five types of PPE and other scarce and critical health and medical resources that FEMA will review and may hold for domestic use prior to export. The objective was to insure that these resources may not be exported from the United States without explicit approval by FEMA. This rule has been extended to remain in effect until June 30, 2021.

FEMA, along with Customs and Border Protection (CBP), the Department of State, the Department of Commerce, the Department of Health and Human Services, and the Food and Drug Administration (FDA), will review U.S. export shipments regularly to insure compliance with this amended TFR.

### **Q & A**

#### **Q1: What are the five critical health and medical resources that are covered by this action?**

A1: The five specified PPE articles are:

- Surgical N95 Filtering Facepiece Respirators
- PPE surgical masks as described by 21 CFR 878.404

- PPE nitrile gloves, specifically 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
- Syringes and hypodermic needles (whether distributed separately or attached together)

**Q2: How long is this TFR extension by FEMA?**

A2: This TFR with modification remains in effect until June 30, 2021, unless sooner modified or terminated by the Administrator.

**Q3: Are the various export exemptions still in place that FEMA listed last year?**

A3: Yes, FEMA still allows exemptions. US exporters should be aware that certain exemptions will still require a Letter of Attestation (LOA). All of the various exemptions and the information on the LOA are in the FEMA Fact Sheet provided in the Resources section below.

**Q4: Can FEMA add other PPE to this list of covered articles?**

A4: Yes. Upon determination that additional items are scarce and necessary for national defense, and to avoid significant disruption to the domestic markets, the Administrator may designate additional materials as “covered materials” in the list. Any additional items added to the list would be posted in the Federal Register.

**References:**

FEMA Dec. 31, 2020 Final Rule:

<https://www.federalregister.gov/documents/2020/12/31/2020-29060/prioritization-and-allocation-of-certain-scarce-and-critical-health-and-medical-resources-for>

FEMA Fact Sheet on Allocation Rule on Exports of PPE:

<https://www.fema.gov/fact-sheet/allocation-rule-personal-protective-equipment-exports>

RegAlert 21-017 - Changes to FEMA’s U.S. PPE Export Review Process (posted on August 10, 2020)

[https://www.fedex.com/content/dam/fedex/us-united-states/International/images/2020/RegAlert\\_20-017\\_Changes\\_to\\_FEMAs\\_U.S.\\_PPE\\_Export\\_Review\\_Process.pdf](https://www.fedex.com/content/dam/fedex/us-united-states/International/images/2020/RegAlert_20-017_Changes_to_FEMAs_U.S._PPE_Export_Review_Process.pdf)

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