

## FEMA Extends Temporary Final Rule Restricting Certain Exports of PPE

August 12, 2020

### Key Points

- On August 10, 2020, FEMA extended the duration of its restrictions on the export of certain shipments of PPE through December 31, 2020.
- The August 10 notice narrowed the types of PPE covered by the restrictions to certain defined types of surgical (as opposed to industrial) respirators, surgical masks, nitrile gloves, and surgical gowns.
- The August 10 notice also extends 11 exemptions allowing exports of shipments meeting certain criteria that FEMA has established since the export restrictions became effective in April 2020.

### Background

On August 10, 2020, the Federal Emergency Management Agency (FEMA) issued a [notice](#) modifying restrictions to reflect current needs and extending the duration of its restrictions on the export of certain shipments of personal protective equipment (PPE) through December 31, 2020 (the “August 10 notice”). The notice also extends 11 exemptions allowing exports of certain covered PPE shipments meeting identified criteria. The notice went into effect immediately.

As detailed in a previous [Akin Gump client alert](#), FEMA established export restrictions on certain covered PPE products in a [temporary final rule](#) (the “Temporary Final Rule”) issued on April 7, 2020. The Temporary Final Rule authorized U.S. Customs and Border Protection (CBP) to temporarily detain exports of certain covered PPE products. While in CBP custody or constructive custody, the Temporary Final Rule allowed FEMA to review the shipments and determine whether to return the shipment for domestic use, issue a Defense Product Act (DPA) rated order for the shipment, or allow part or all of the shipment to be exported. FEMA has stated that it is undertaking best efforts to provide a determination on each covered export shipment within three business days. Absent the August 10 notice, the Temporary Final Rule would have expired on August 10.

Another previous [Akin Gump client alert](#) detailed 11 exemptions to the export restrictions that FEMA established via [guidance](#) issued on April 17, 2020 (the

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“Guidance”). Covered PPE shipments that qualify for the exemptions, including documentation requirements as applicable, are permitted to leave the United States without FEMA’s explicit approval.

## **Modifications to Covered PPE**

The August 10 notice modifies the Temporary Final Rule by reducing the list of covered materials to four types of PPE in order to reflect current domestic demand. FEMA identified domestic demand using the number of open requests for such materials from state, local, Tribal, and territorial jurisdictions. Accordingly, covered PPE is now limited to the following items:

1. 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.
2. PPE surgical masks, including masks that cover the user’s nose and mouth and provide a physical barrier to fluids and particulate materials.
3. 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.
4. 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.

The August 10 notice thereby reduces the list of materials covered by FEMA’s export restrictions from five to four types of PPE. The notice modifies the former description of covered N95 Filtering Facepiece Respirators by adding the word “surgical” to the description “[b]ecause [high] demand is specific to surgical N95 respirators and does not include industrial respirators.” Industrial respirators are therefore no longer subject to export restrictions. Similarly, the August 10 notice narrows the scope of covered gloves to solely the nitrile types specified above because “[d]omestic supply for latex and vinyl examination and surgical gloves has largely caught up with demand,” justifying their removal from the scope of covered gloves. The August 10 notice also removes two items from the list of covered PPE: (1) “other filtering facepiece respirators”; and (2) “elastomeric, air-purifying respirators and appropriate particulate filters/cartridges.” By contrast, the August 10 notice adds restrictions for the specified types of surgical gowns, which were not previously subject to export restrictions.

## **Eleven Exemptions Remain in Place**

The August 10 notice expressly extends the exemption established by the Temporary Final Rule for “shipments made by or on behalf of U.S. manufacturers with continuous export agreements with customers in other countries since at least January 1, 2020, so long as at least 80 percent of such manufacturer’s domestic production of covered materials, on a per item basis, was distributed in the United States in the preceding 12 months.”

The August 10 notice also extends the exemptions and applicable documentation requirements for ten additional categories of shipments established in its April 17 Guidance as follows:

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).
3. Intracompany Transfers of Covered Materials by U.S. Companies from Domestic Facilities to Company-owned or Affiliated Foreign Facilities.
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.
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. These May be Shipped via Intermediaries (Logistics Providers) but are Shipped from and Consigned to Foreign Governments.
7. Shipments to Overseas U.S. Military Addresses, Foreign Service Posts (e.g. Diplomatic Post Offices), and Embassies.
8. In-Transit Merchandise: Shipments in Transit through the United States with a Foreign Shipper and Consignee, Including Shipments Temporarily Entered into a Warehouse or Temporarily Admitted to a Foreign Trade Zone.
9. Shipments for Which the Final Destination is Canada or Mexico.
10. Shipments by or on behalf of the U.S. Federal Government, including its Military.

FEMA established an additional exemption for certain surplus covered PPE materials via [guidance](#) issued on its website on July 6, 2020. That exemption allowed exporters with “a surplus of a covered material [who] can demonstrate a good-faith and unsuccessful attempt to sell the material domestically, . . . [to] submit a request to FEMA to allow the material to be exported.” However, that exemption is not expressly addressed in the August 10 notice, and it is therefore unclear whether it has been extended.

### **Guidance for the Customs and Export Communities**

Aside from the changes to covered PPE highlighted above, FEMA’s export restrictions on those products remain largely the same as originally established under the Temporary Final Rule. FEMA will accordingly continue to implement the Temporary Final Rule in conjunction with CBP and other applicable agencies. FEMA may also continue to provide additional guidance regarding the application of any exemptions to the restrictions and may establish additional exemptions, as appropriate.

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