



## International Trade & Regulatory ADVISORY ■

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### FEMA Issues Guidance on Exemptions for Critical PPE Export Restrictions

On Friday April 17, 2020, the Federal Emergency Management Agency (FEMA) filed a notification on the public inspection list identifying 10 exemptions to a temporary export control rule ("FEMA Rule") that was published on April 7, 2020, restricting the export of certain personal protective equipment (PPE) required for the U.S. medical response to the COVID-19 pandemic. The 10 [exemptions](#) took effect upon publication.

#### **Background on the FEMA Rule**

The temporary [FEMA rule](#), issued on April 7, 2020, was enacted as a response to the Presidential Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use, an order issued by President Trump on [April 3, 2020](#). The presidential memorandum and FEMA Rule designated five different categories of PPE that were to be prioritized and allocated for domestic use. The FEMA Rule directs U.S. Customs and Border Protection (CBP) to temporarily detain any shipment of those PPE categories to allow FEMA the opportunity to "determine whether to return for domestic use, issue a rated order for, or allow the export of part or all of the shipment." This temporary rule was issued in accordance with the Administration's recent invocation of the Defense Production Act (DPA).

#### **Current PPE Export Restrictions**

The FEMA Rule established that effective April 7 – for a period of 120 days – the following categories of PPE are considered to be "scarce or threatened materials" and are immediately restricted for export:

- 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;
- Other Filtering Facepiece Respirators (e.g., those designated as N99, N100, R95, R99, R100, or P95, P99, P100), including single-use, disposable half-mask respiratory protective devices that cover the user's airway (nose and mouth) and offer protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181;
- Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges;

- PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials; and
- PPE gloves or surgical gloves, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such gloves intended for the same purposes.

It is worth noting that while this rule only covers these categories of PPE, it also provides the FEMA administrator with authority to designate additional products that are determined to be scarce or threatened. With reported shortages of medical testing kits, testing swabs, cleaning supplies, and other essential hospital items, exporters should brace for additional designations by FEMA if short supply continues or worsens over the coming weeks.

## Interim CBP Guidance and Exemptions Formally Issued by FEMA

In an [internal memorandum](#) that was released a few days after the publication of the FEMA Rule, CBP issued certain exclusions to the export restrictions for CBP Field Operations to reference when clearing shipments. In this memo, CBP signaled that FEMA is focused on restricting the export of "commercial quantities" of PPE, which is defined as shipments valued over \$2,500 and containing more than 10,000 units of gloves, masks, or other commodities. CBP also listed certain circumstances that are deemed to be excluded from the FEMA rule:

- Exports to Canada or Mexico;
- Exports to U.S. Government entities such as U.S. military bases overseas;
- Exports by U.S. Government agencies;
- Exports by U.S. charities;
- Exports by critical infrastructure industries for the protection of their workers;
- Exports by the 3M Company;
- Express or Mail Parcels that do not meet the commercial quantity definition above;
- In-transit shipments.

FEMA then published a list of official exemptions to its temporary rule. These 10 exemptions are:

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 PPE materials by nonprofit or nongovernmental organizations that are solely for donation to foreign charities or governments for free distribution.
3. Intracompany transfers of covered PPE materials by U.S. companies from domestic facilities to company-owned or affiliated foreign facilities.
4. Shipments of covered PPE 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 when only a portion of the kit is made up of one or more covered PPE 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 U.S. military addresses and foreign service posts.
8. In-transit merchandise.
9. Shipments for which the final destination is Canada or Mexico.
10. Shipments by or on behalf of the U.S. federal government, including the military.

## What Should Exporters Know About the New Exemptions?

While there are some exemptions that overlap with the CBP guidance, exporters should rely on the FEMA exemptions and not the earlier CBP memorandum. In order to claim FEMA exemption 2, 3, 4, 8, or 9, the exporter must submit a letter of attestation to CBP's document imaging system certifying the specific purpose of the shipment. This certification letter must 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.

## Final Takeaways

Through this latest notice, FEMA maintains discretion to publish additional exemptions. It is also within FEMA's discretion to waive an exemption invoked by an exporter if determined that "it is necessary or appropriate to promote the national defense." Because FEMA is not a typical federal agency administering export controls, it is not clear how fast clearances or approvals will be issued when exporters seek to ship covered PPE materials under an exemption.

Exporters are encouraged to closely monitor the situation involving these new export control rules and should expect further developments as more PPE becomes available for shipment. Exporters and customs professionals should expect delays and even diversions of shipments originally destined for locations outside the U.S.

Alston & Bird has formed a multidisciplinary [task force](#) to advise clients on the business and legal implications of the coronavirus (COVID-19). You can [view all our work](#) on the coronavirus across industries and [subscribe](#) to our future webinars and advisories.

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