

## Trade Compliance Flash: Q&A on Export Restrictions on Personal Protective Equipment (PPE)

International Alert

**04.13.2020**

In response to the COVID-19 epidemic in the United States, the Federal Emergency Management Agency (FEMA) issued a [temporary final rule](#) (the Rule) restricting the export of five categories of personal protective equipment (Covered PPE) from the United States. On April 9, 2020, U.S. Customs and Border Protection (CBP) issued internal [guidance](#) (the CBP Guidance) on the application of the Rule. The Rule implements the Presidential Memorandum dated April 3, 2020, in which the president directed the Department of Homeland Security (DHS) to take action under the Defense Production Act (DPA) to prevent the diversion of necessary medical materials abroad.

Specifically, the Rule requires CBP to temporarily detain any shipment of Covered PPE until FEMA determines whether to permit the shipment or allocate the Covered PPE for domestic use. FEMA's determination will be based on a number of factors, explained below, including any need to ensure that "scarce or threatened" items used to treat or prevent COVID-19 are allocated for domestic use. Further, the CBP Guidance provides a list of exports that are excluded from the Rule's application.

The Rule is effective immediately and will remain in effect for 120 days from the date of the Rule's [publication](#) in the Federal Register—*i.e.*, until August 8, 2020. Members of the public may be able to provide comments if the Rule is extended or made permanent.

Our answers to the most important questions relating to the Rule are set forth below, including those regarding the products covered, FEMA's review process, and applicable penalties.

### What are the Covered PPE Subject to the Rule?

The five categories of Covered PPE listed in the Rule are:

- 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, P95, P99, or 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
- 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

These categories of PPE are the same as those described in the Presidential Memorandum under the DPA. However, they are only five of the 15 categories of products previously designated as "scarce or threatened" in connection with the COVID-19 epidemic in a Department of Health and Human Services Notice (HHS Notice). The HHS Notice also included certain ventilators, ventilator accessories, sterilization services, disinfecting devices, and other products which are not currently restricted

for export but may become so in the future.

## To Whom Does the Rule Apply?

The Rule is applicable to all persons involved in the export of Covered PPE. The Presidential Memorandum and the Rule both state that "it is the policy of the United States to prevent domestic brokers, distributors, and other intermediaries from diverting" Covered PPE overseas. Further, FEMA may apply for injunctions or restraining orders against "any person" that FEMA believes has engaged or is about to engage in a violation of the Rule and that "any person" who willfully violates the Rule is subject to penalties and imprisonment.

## Are There Any Exclusions or Exemptions to the Rule?

Both FEMA and CBP have emphasized that they do not view the purpose of the Rule as prohibiting all exports of Covered PPE outside of the United States. Rather, the focus is on restricting commercial exports of a certain character and volume. Accordingly, the Rule issued by FEMA, the CBP Guidance, and informal guidance provided by FEMA/CBP provide for certain exclusions and exemptions that may (a) prevent shipments from being detained by CBP in the first instance, or (b) allow for the release of any detained shipments. If the Covered PPE falls within an exclusion, then it should not be a target for detention so long as the shipment's documentation properly reflects that an exclusion applies. If the Covered PPE falls within the exemption, then the shipment will be subject to detention pending FEMA's review of whether the shipment meets the exemption's criteria.

We summarize the exclusions and the exemption below:

- **Non-commercial shipments:** The CBP Guidance confirms that the focus of the Rule will be shipments in "commercial quantities," defined to mean shipments valued at \$2,500 or more and containing more than 10,000 units of Covered PPE. Shipments below this threshold are not likely to be detained by CBP or, at worst, are likely to be released from detention by CBP without the need for FEMA's review.
- **Intra-company transfers:** Informally, FEMA has confirmed that the purpose of the Rule is not to stop intra-company transfers of Covered PPE that are not for sale to a third party. Such Covered PPE may have legitimate non-medical use in oil and gas, construction, and other industries. FEMA has informally recommended that exporters include a "letter of attestation" when this exclusion applies.
- **Exports to Canada or Mexico**
- **Exports to U.S. government entities such as U.S. military installations 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**
- **In-transit shipments**
- **Exemption for certain U.S. manufacturers:** The Rule provides an explicit exemption for shipments where the (a) shipment is made by or on behalf of U.S. manufacturers that have had continuous export agreements with foreign customers since at least January 1, 2020, and (b) 80 percent of the manufacturer's products covered by the Rule (on a per item basis) were distributed within the United States over the preceding 12 months. After FEMA determines that the shipment falls within the exemption, the Covered PPE may be exported without further review. However, FEMA retains the ability to waive the exemption and fully review the shipment if FEMA determines that doing so "is necessary or appropriate to promote the national defense."

When issuing the Rule, FEMA made clear that it may announce new exemptions in the Federal Register if FEMA determines that a new exemption is "necessary or appropriate to promote the national defense." FEMA may also develop additional guidance on which exports are covered by the current exemption and encourages manufacturers to contact FEMA with specific information about their eligibility for the exemption.

## **What is the Review Process When Covered PPE Is Presented for Export?**

As noted above, the Rule requires CBP to temporarily detain any shipment of Covered PPE until FEMA determines whether to permit the shipment of such products or to allocate them for domestic use. The CBP Guidance provides that U.S. port personnel will determine whether a shipment contains Covered PPE based on information and documents disclosed in the relevant Electronic Export Information (EEI), which must be filed through CBP's Automated Export System (AES) for most exports. Physical examination of the shipment is also possible.

After the shipment is detained, CBP will inform FEMA about the shipment's intended export and FEMA will conduct a review. FEMA's review will determine whether:

- The shipment will be returned for domestic use;
- FEMA will use the authorities granted under the DPA to issue a rated order for all or part of the shipment (i.e., require that some or all the Covered PPE be sold to FEMA); or
- FEMA will allow the export of all or part of the shipment.

The Rule requires FEMA to reach a determination "within a reasonable timeframe after notification of an intended export." FEMA's review will consider the totality of the circumstances, including the following factors:

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

The Rule does not specify compensation exporters may receive if their products are allocated for domestic use. The Rule provides two types of allocation for domestic use. First, FEMA may determine to "return [the shipment] for domestic use," which implies that the exporter will be able to sell the products in the domestic market. Second, FEMA may "issue a rated order for part or all of the shipment, pursuant to" the DPA, meaning that compensation of the required sale to FEMA will be governed by the DPA.

Although the export requirements for Covered PPE are generally minimal, it is important to note that the Rule does not impact existing economic sanctions and export controls, which may continue to apply even if FEMA allows a shipment of Covered PPE. Exporters should remain cognizant of the applicability of such laws and ensure compliance for any outbound shipments of Covered PPE.

## **What are the Penalties for Not Complying with the Rule?**

Under Sections 705 and 706 of the DPA, FEMA is authorized to (a) conduct investigations, request information or testimony, and

inspect records or premises, and (b) seek permanent or temporary injunctions, restraining orders, or other orders to enforce compliance with the Rule. We anticipate that FEMA is likely to use these authorities not only with regard to manufacturers and exporters, but also "domestic brokers, distributors, and other intermediaries" – parties specifically mentioned in the Presidential Memorandum under the DPA.

In addition, any person who willfully violates the Rule is subject to a penalty of up to \$10,000 and can be imprisoned for up to one year under Section 103 of the DPA. Further, under 18 U.S.C. § 554 (Smuggling Goods from the United States), anyone who fraudulently or knowingly exports anything from the United States contrary to U.S. law, or who facilitates such a transaction, can face fines and/or up to 10 years of imprisonment.

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As events around the COVID-19 crisis unfold, and the government continues to act in response, affected and potentially affected companies and individuals would be advised to proactively consider how to respond and prepare.

Miller & Chevalier has the experience and expertise to help you navigate these new FEMA and CBP export requirements as well as future restrictions. Together, our [Customs & Import Trade](#) and [Economic Sanctions & Export Controls](#) teams have extensive experience handling matters before government agencies, including negotiating the release of merchandise detained by CBP and obtaining authorization from the Department of Commerce's Bureau of Industry and Security (BIS) for the export of restricted items. As government responses to the COVID-19 crisis rapidly are developing, we can ensure that you are in compliance with any new export restrictions, help you submit comments to the government, and advocate on your behalf before government agencies and Congress.

Given the ongoing nature of the COVID-19 crisis and the government's actions, we will continue to update this Q&A as appropriate.

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