



COVID-19 Update

April 2020

FEMA Announces Export Restrictions on Personal Protective Equipment (PPE)

Key Notes:

- Effective April 7, 2020, most exports from the United States of certain respirators, masks and gloves require approval from FEMA.
- Restrictions continue until August 8, 2020.

On April 7, 2020, the U.S. Department of Homeland Security's Federal Emergency Management Agency ("FEMA") issued a [temporary final rule](#) ("Rule") to establish export restrictions on certain types of personal protective equipment products ("PPE") used in the response to the COVID-19 pandemic. The Rule implements the [Presidential Memorandum](#) dated April 3, 2020, in which President Trump directed Homeland Security to take action under the Defense Production Act of 1950 (50 U.S.C. § 4501) to prevent diversion of the necessary materials overseas. Although the Rule will not be published in the Federal Register until April 10, 2020, it became effective immediately and will remain in effect for 120 days from its publication, until August 8, 2020.

The Rule covers some, but not all, of the 15 categories of materials the U.S. Department of Health and Human Services identified as "scarce or threatened materials" in a [notice](#) last week. Specifically, the PPE covered by the Rule are:

- N-95 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).

The Rule applies to all persons involved in the export of the covered PPE from the United States, including "manufacturers, brokers, distributors, exporters, and shippers." The Rule provides that all shipments of the covered PPE will be "temporarily detained" by U.S. Customs and Border Protection while FEMA determines whether to:

- (1) Return the shipment for domestic use;
- (2) Issue a rated order under the DPA; or
- (3) Allow the export of part or all of the shipment.

In reaching a determination about a particular shipment, the Rule states that FEMA will consider the totality of the circumstances, including the following:

- 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 any potential hoarding or price-gouging concerns;
- The quantity and quality of the materials;
- Humanitarian considerations; and
- International relations and diplomatic considerations.

Notably, the Rule contains a limited exemption for covered PPE “from 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% of such manufacturer’s domestic production of these materials was distributed in the U.S. in the preceding 12 months.” If FEMA determines that a shipment of covered PPE falls within this exemption, the shipment may be transferred out of the United States without further review by FEMA. Additional guidance on this exemption from FEMA appears to be forthcoming.

FOR MORE INFORMATION

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Additional Resources

We have assembled a firmwide multidisciplinary task force to address clients’ business and legal concerns and needs related to the COVID-19 pandemic. Please see our [COVID-19 Task Force](#) page for additional information and resources.

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