

FEMA Issues Restrictions on PPE Exports Due to COVID-19 Pandemic

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On April 10, 2020, the U.S. Federal Emergency Management Agency (FEMA) published a [Temporary Final Rule](#) as part of its response to the COVID-19 pandemic. The Temporary Final Rule allocates certain scarce or threatened materials used for domestic use may not be exported from the United States without explicit approval by FEMA. The rule covers five types of personal protective equipment (PPE). Under the Temporary Final Rule, U.S. Customs and Border Protection (CBP) will temporarily detain any export shipment of covered PPE and the FEMA Administrator will determine whether to return for domestic use or issue a rated order for part or all of the shipment. This rule is effective from April 7, 2020 until August 10, 2020.

The Temporary Final Rule requires FEMA to make its determination “within a reasonable timeframe” after being notified by CBP. In determining whether it is necessary or appropriate to promote the national defense to purchase covered materials, or allocate materials for domestic use, FEMA may consult other agencies and will consider the totality of the circumstances, including the following factors:

- (1) The need to ensure that scarce or threatened items are appropriately allocated for domestic use;
- (2) minimization of disruption to the supply chain, both domestically and abroad;
- (3) the circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns;
- (4) the quantity and quality of the materials;
- (5) humanitarian considerations; and
- (6) international relations and diplomatic considerations.

The FEMA rule includes a single exemption - for covered materials that are made by or on behalf of U.S. manufacturers with continuous export agreements with customers in other countries. And the exemption only applies if at least 80% of that manufacturer’s domestic production was distributed in the U.S. in the past year.

The covered materials under the FEMA rule are the following:

- (1) 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) 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;
- (3) Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges;
- (4) PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials; and
- (5) 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.

On April 9, 2020, CBP issued a memorandum to CBP Ports providing guidance to implement the FEMA temporary rule. FEMA has conveyed to CBP that the focus of the effort is on commercial quantities. Commercial quantities are currently defined as shipments valued at \$2,500 and above and containing 10,000 units or more. Furthermore, the CBP guidance provides that the following circumstances are also excluded:

- 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 may conduct investigations and issue requests for information as may be necessary for the enforcement of the Defense Production Act of 1950, including this rule. In addition to FEMA seeking an injunction, failure to comply fully with this rule is a crime punishable by a fine of not more than \$10,000 or imprisonment for not more than one year, or both. Further, anyone who fraudulently or knowingly exports articles contrary to law or regulation, or facilitates such a transaction, can face fines and/or up to 10 years' imprisonment under 18 U.S.C. § 554.

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