

United States Bans Exports of Certain Personal Protective Equipment with Potential for Further Export Restrictions

by Lawrence Ward and Dave Townsend

The Federal Emergency Management Agency (“FEMA”) has banned the export from the United States of certain masks, respirators and respirator parts, and medical gloves used as personal protective equipment (“PPE”) through a new government order effective on April 7 and published in the Federal Register on April 10 (“the FEMA Order”). FEMA is an agency within the U.S. Department of Homeland Security (“DHS”). The FEMA Order is based upon the U.S. Government’s determination that preserving and protecting the domestic supply of these PPE items is necessary to respond appropriately to the COVID-19 crisis in the United States and to protect U.S. national security.

Statutory Basis. The FEMA Order was issued under Section 101 of the Defense Production Act of 1950 (“DPA”), which allows the President to require performance under contracts or orders deemed necessary to promote national defense over the performance of any other contract, and to allocate materials in a manner deemed necessary for national defense. The FEMA Order implements an April 2 Presidential memorandum, drawing upon emergency powers provided under the DPA, that had directed FEMA and DHS to acquire from the 3M Company the number of N-95 respirators (filtered masks) that the FEMA Administrator deemed “appropriate” to meet U.S. requirements. The Administration and 3M negotiated to balance the U.S. and non-U.S. requests for 3M-produced N-95 masks in the coming months. FEMA had to be satisfied that the United States would have enough N-95 masks in the domestic inventory while 3M had to believe it would have enough masks also to meet its own contractual and humanitarian commitments to supply such masks to Canada and Latin America.

Affected PPE Items. The FEMA Order applies to the five following types of PPE items that are physically within the United States, regardless of their country of origin:

- N-95 facepiece respirators, including half-face-piece masks intended to cover the nose and mouth of the wearer to reduce exposure to airborne particulates;
- Other respirators not designated as N-95, including single-use, disposable masks;
- Elastomeric air-purifying respirators and appropriate filters and cartridges for such

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- masks;
- Surgical masks that cover the user's nose and mouth providing a physical barrier to fluids and airborne particulate materials; and
- Gloves and surgical gloves.

Other Potentially Affected PPE Items. The FEMA Order states that FEMA may add additional items to the export ban at any time upon finding that they are scarce under the DPA and critical for an effective national response to the COVID-19 outbreak. In designating the five PPE items under the FEMA Order, FEMA relied on an earlier finding issued on March 25 by the U.S. Department of Health and Human Services ("DHHS") that those covered PPE items are "scarce."

Companies who deal in such PPE items should take note that the March 25 DHHS order had also designated ten other classes of PPE items as "scarce." Although these ten other categories of PPE gear were not named in the FEMA Order, and accordingly are not currently subject to the U.S. export ban, the FEMA Order clearly leaves the door open for FEMA to add additional "scarce" PPE items to the FEMA Order. Those ten other types of "scarce" PPE items include:

- (1) Powered air purifying respirators;
- (2) Portable ventilators such as those for delivering oxygen;
- (3) Drugs with the active ingredient chloroquine phosphate or hydroxychloroquine HCl;
- (4) Sterilization services for certain devices;
- (5) Disinfecting devices and disinfecting products including sanitizing products suitable for use in a clinical setting;
- (6) Medical gowns or apparel;
- (7) PPE coveralls;
- (8) PPE face masks;
- (9) PPE face shields; and
- (10) Ventilators, anesthesia gas machines, positive breathing devices, and certain accessories for those items.

FEMA Order Enforcement & Penalties. The FEMA Order authorizes U.S. Customs and Border Protection ("CBP") to seize and detain any PPE items that are listed in the FEMA Order and intended for export. After CBP acts to block such an export shipment, then FEMA may consider whether to return the covered PPE items for domestic use, to issue a DPAS-rated order for the U.S. Government to buy the items, or to allow the export of part or all of the shipment. The FEMA Order also imposes stiff criminal penalties for violations or attempted violations. The penalties under the FEMA Order can be up to \$10,000 per violation, and include up to ten years in prison.

FEMA-Administered Exemption Process for Permissible Exports. The FEMA Order does allow a U.S. company to export any of the covered PPE items if that company applies for and receives an exemption from FEMA. The FEMA Order indicates that FEMA may grant such an exemption to a company based on a variety of factors, including the scarcity of the PPE items and humanitarian and international relations considerations. Another basis for exemption is if the company has pre-existing

contractual obligations to supply the items to non-U.S. destinations that were in effect since at least January 1, 2020 and, in addition, the company had distributed at least 80% of its domestic production of such covered PPE items in the United States within the last 12 months. FEMA must make an affirmative determination with respect to a company's eligibility prior to granting any such exemption under the FEMA Order, which means that the company seeking such an exemption bears a considerable burden of persuasion to document its eligibility under these legal standards. The agency states that it will consider such exemption requests "quickly and will endeavor to minimize disruptions to the supply chain."

Recommended Actions. Any U.S. company making, distributing, or shipping any of the PPE items subject to the FEMA Order should consider these steps:

- The company should immediately determine if its business activities would lead to export of those PPE items to a foreign country. If so, the company then needs to consider whether it could legitimately seek an exemption from the FEMA Order or must inform the foreign customer or buyer that the company is no longer allowed to export the items as originally planned and then to try to reach some reasonable accommodation;
- The company should review all of its business agreements concerning items subject to the FEMA Order to be sure such agreements contain a clear and robust *force majeure* provision that would protect the company against breach of contract claims by any aggrieved foreign customer or buyer if the FEMA Order or other federal intervention blocks the company's fulfillment of any such contract to export the affected items; and
- The company should review any existing or future customer or buyer purchases of items subject to the FEMA Order and, if feasible, obtain written customer or buyer assurances that such purchases are only for domestic U.S. use or resale and are not intended to lead to exports contrary to the FEMA Order.

In addition, if any U.S. company makes, distributes, or ships any of the other ten categories of PPE items that were listed as "scarce" in the March 25 DHHS order but that were not subject to the FEMA Order, the company should probably do some prompt contingency planning. It should quickly consider what a potential future FEMA DPA-based directive similar to the FEMA Order or other comparable U.S. Government directive would mean for its business relationships and contractual commitments. This would mean assessing future company exports or contractual obligations to support future exports, reviewing agreements for *force majeure* provisions to avoid contractual liability as the result of obeying such directives, and perhaps identifying potential non-U.S. suppliers that could be alternative sources to meet such obligations while remaining compliant with the FEMA Order.

Dorsey & Whitney attorneys can assist in reviewing the FEMA Order and answer questions about its scope and effect. Our attorneys are closely following the actions of FEMA, DHS, DHHS and other U.S. Government agencies that may affect the ability of U.S. companies to export such PPE items from the United States.

