International Trade Alert

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CBP Authorized to Detain Certain Exports of Health and Medical Materials Pursuant to FEMA Temporary Rule

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Key Points

- Beginning April 7, 2020, CBP is authorized to temporarily detain all shipments of five categories of personal protective equipment used in the response to and treatment of COVID-19, pursuant to a Temporary Rule issued by FEMA.
- FEMA issued the Temporary Rule to ensure that scarce or threatened supplies of personal protective equipment remain in the United States for domestic use.
- Under the Temporary Rule, CBP will detain certain exports while FEMA reviews and determines whether the shipment must be returned for domestic use, issued a rated order for or allow part or all of the shipment to be exported.
- In issuing the Temporary Rule, the United States joins a growing number of nations imposing export restrictions on PPE and other medical products used to respond to COVID-19.

Background

On April 7, 2020, the Federal Emergency Management Agency (FEMA) issued a temporary final rule (the "Temporary Rule") in the Public Inspection issue of the *Federal Register* that establishes export restrictions on five types of personal protective equipment (PPE) and authorizes U.S. Customs and Border Protection (CBP) to temporarily detain exports of those products. FEMA asserted that the Temporary Rule became effective immediately upon its appearance in the Public Inspection issue. The Temporary Rule will stay in effect until 120 days from its final publication, currently scheduled for April 10, 2020, i.e., August 8, 2020.

FEMA issued the Temporary Rule to aid the U.S. response to the spread of COVID-19 by allocating certain "scarce or threatened health and medical resources for domestic use." The Temporary Rule is issued under Sections 101 and 704 of the Defense Production Act of 1950 (DPA) and implements the Presidential Memorandum of April 3, as well as Executive Orders 13909, 13910 and 13911.

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Covered Materials

Under the Temporary Rule, all shipments of the following five covered materials must be allocated for domestic use and may not be exported from the United States without explicit approval by FEMA.

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.
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.

Review Process and Narrow Exemption for Covered Materials

CBP will temporarily detain all shipments of the covered materials listed above and will notify FEMA of the intended exportation. While each shipment is in CBP custody or its constructive custody, FEMA will determine whether to return the shipment for domestic use, to issue a DPA-rated order for the shipment, or to allow the exportation of part or all of the shipment.

The Temporary Rule requires FEMA to make its determination "within a reasonable timeframe" after being notified by CBP. FEMA's determination will consider the "totality of the circumstances" along with the following factors, after possible consultations with other agencies:

1. The need to ensure that scarce or threatened items are 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.
6. International relations and diplomatic considerations.

Certain shipments of covered materials may be exempted from the Temporary Rule if made by or on behalf of U.S. manufacturers with continuous export agreements with customers abroad since at least January 1, 2020. To qualify for the exemption, however, the manufacturer must also have distributed at least 80 percent of its domestic production of the covered materials, on a per item basis, within the U.S. in the preceding 12 months. If FEMA determines that a manufacturer's shipment is

exempted, it may be exported without further review. However, FEMA retains sole discretion to waive the exemption and fully review such shipments if it is "necessary or appropriate to promote the national defense."

Implications for the Customs and Export Communities

Exporters of covered PPE products are subject to the Temporary Rule, and any other parties that facilitate such exports contrary to the Temporary Rule are subject to a risk for enforcement and penalties. To ensure compliance, FEMA may conduct investigations, request information or testimony, and inspect records or premises. Exporters and other parties in the supply chain such as carriers and forwarders should keep these investigatory powers in mind when preparing shipments of covered PPE materials for export.

Violations and potential violations of the Temporary Rule are subject to FEMA enforcement via injunctions, restraining orders or other similar orders. Additionally, penalties for violations are authorized under the DPA, including fines up to $10,000 and/or imprisonment for no more than one year. 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.

CBP's process for detaining shipments is not yet clear. CBP may identify shipments for detention and FEMA approval based on, for example, commercial invoices, bills of lading, known shippers and tariff classifications, and will likely scrutinize applicable electronic export information (EEI) filings and export manifests. In any case, all PPE products and other medical-related goods may face significant delays as CBP begins to exercise the detention authority. CBP already has limited capacity due to federal social distancing guidelines and a surge of imported products subject to FDA clearance.

The Temporary Rule effectively creates a new mechanism to restrict and control exports under the DPA without relying on the existing U.S. export control system. However, exporters should note that this novel mechanism and new authorities do not override other export control and sanctions obligations pertaining to exports to proscribed persons or embargoed destinations, absent exceptions applicable under those legal authorities. Existing requirements relating to the provision of EEI also continue to apply. Instead, the new mechanism essentially allows FEMA to make case-by-case determinations as to whether specific shipments should be subject to a DPA-rated order, rather than issuing a blanket rated order for covered PPE materials up front.

FEMA notes that it may develop additional guidance and encourages manufacturers to contact FEMA with specific information regarding their status under this exemption. FEMA also retains discretion to establish further exemptions. The Temporary Rule does not contemplate other opportunities for public comment at this time because FEMA asserted an exemption under Section 709(b) of the Administrative Procedures Act contending that the emergency nature of the action makes advance notice and public comment "impractical, unnecessary, or contrary to the public interest." However, interested parties might still opt to file comments with FEMA even though the agency has not formally solicited them.

Additionally, the materials covered under the Temporary Rule represent only five of fifteen categories that the Department of Health and Human Services (HHS) identified

as “scarce or threatened materials” in a notice issued on March 25, 2020. It is possible that the other ten categories—including products such as ventilators, disinfecting devices, medical gowns, face shields and drugs containing chloroquine phosphate or hydroxychloroquine HCl—could be subject to future restrictions.

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