

## COVID-19: NEW FEMA RULE LIMITS U.S. EXPORT OF PERSONAL PROTECTIVE EQUIPMENT

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### U.S. International Trade Alert

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The U.S. Federal Emergency Management Agency (FEMA) has issued a temporary rule, pursuant to Section 101 of the federal Defense Production Act (DPA), under which FEMA will review and limit export shipments of five types of personal protective equipment (PPE) to ensure that there are sufficient supplies for domestic use. As detailed below, FEMA must in effect explicitly approve all export shipments from the United States of “covered materials” (including certain types of facemasks, respirators, and gloves), which are to be detained by U.S. Customs and Border Protection (CBP) pending FEMA review. This rule is currently effective and, unless extended, will expire on August 10, 2020.

### COVERED MATERIALS

The FEMA Administrator has designated the following PPE as “covered materials” subject to FEMA's export review:

- 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, 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 C.F.R. § 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 C.F.R. §§ 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such gloves intended for the same purposes.

If necessary, the FEMA Administrator may expand this list of covered materials to include additional items. Additions would be based on a determination that the subject items are scarce, that they are necessary for national defense, and that an allocation order is the only way to meet requirements without significant disruption to the domestic markets.

### FEMA PERMISSION TO EXPORT

The temporary rule establishes a process for FEMA to review export shipments of covered materials. Under this process, CBP detains shipments temporarily to allow time for FEMA to review the proposed shipments and determine whether the covered materials should be permitted to be exported or, alternatively, required to be returned for domestic use or made subject to a DPA-rated order (in which case, the goods are consigned to FEMA pending further distribution or direction). FEMA is not subject to any deadlines, but the temporary rule states that determinations will be made within a reasonable time of FEMA being notified of an intended shipment.

The six factors FEMA will consider in reviewing proposed exports of covered materials are:

- 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; and
- International relations and diplomatic considerations.

## **CBP GUIDANCE**

CBP issued guidance on April 9, 2020, regarding how FEMA's temporary rule will be implemented. Of particular note, the guidance explains that FEMA will focus its export review on "commercial quantities" of covered materials. Commercial quantities are defined in the guidance as shipments valued at \$2,500 or more and containing more than 10,000 units of covered materials. In addition, CBP notes that the following exports will be "excluded" from FEMA review:

- 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.

At each U.S. port of export, CBP will target shipments of commercial quantities of covered materials that do not meet the exclusions above and will conduct document reviews and physical examinations of such shipments, as necessary, to determine if the items in question fit the definition of "scarce or threatened" "covered materials" under the FEMA temporary rule. Presumably, FEMA would then conduct its review of the shipments identified by CBP.

## EXEMPTION

In addition to the exceptions referenced in CBP's 9 April guidance, FEMA established a narrow "exemption" that is intended to mitigate the negative impact of the temporary rule on pre-existing commercial relationships, the international supply chain, and humanitarian efforts. This exemption applies when: (1) the covered materials are made by or on behalf of U.S. manufacturers; (2) the shipment is pursuant to continuous export agreement with a foreign customer, executed on or before 1 January 2020; and (3) at least 80% of the manufacturer's domestic production of covered materials, on a per-item basis, was distributed in the United States in the preceding 12 months.

If FEMA determines that a shipment of covered materials falls within this exemption, the materials may be transferred out of the United States without further review by FEMA. However, the temporary rule nonetheless permits the FEMA Administrator to waive this exemption and fully review a shipment qualifying for the exemption if doing so is necessary or appropriate to promote the national defense.

FEMA has indicated that it may provide further guidance regarding this exemption, and it encourages manufacturers to contact FEMA with specific information regarding the status of proposed shipments under this exemption.

## ENFORCEMENT

FEMA will implement and enforce this rule in cooperation with other agencies, including CBP. Failure to comply fully with FEMA's temporary rule can be a criminal offense under the DPA, punishable by a fine of not more than \$10,000 or imprisonment for not more than one year, or both. Moreover, the temporary rule notes that, under 18 U.S.C. § 554, whoever fraudulently or knowingly exports or attempts to export covered items contrary to any U.S. law or regulation, or knowingly receives, conceals, buys, sells, or facilitates the transportation, concealment, or sale of such items, faces up to 10 years' imprisonment, a fine, or both, if convicted. Presumably, depending on the circumstances of any shipment in violation, infractions of other CBP and federal laws and regulations could occur, such as those relating to false statements.

## POTENTIAL IMPLEMENTATION MEASURES

It is possible that FEMA or CBP will either formally or informally adopt additional protocols or procedures in connection with implementing the temporary rule. For example, FEMA apparently has indicated that, in cases of intra-company transfers qualifying to be excluded from FEMA review, the exporter should include a "letter of attestation" on company letterhead with the shipment, stating that the PPE is "not for sale and is for internal company use" and also stating the relationship of the consignee to the consignor. We also understand that FEMA may be issuing a form that could be submitted by export shippers of covered PPE to facilitate pre-shipment clearances under the rule.

## CONCLUSION

Given the unusual nature of the temporary rule, the likely challenges to its implementation, the absence of enforcement precedents, and FEMA's lack of experience in enforcing export controls, U.S. exporters should exercise special care when making shipments subject to the new rule. Indeed, prior to any attempted export of

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covered material, it would be advisable to consult with counsel or with the agencies involved regarding any further formal or informal developments to ensure compliance risks are minimized.

If you have any questions regarding FEMA's temporary rule please contact any member of the International Trade group listed above.

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