

FEMA releases exceptions to rule prohibiting exports of PPE – exports to Canada and Mexico are excluded and other important exclusions apply

20 April 2020

On 17 April the Federal Emergency Management Agency (FEMA) released significant exceptions (effective Friday 17 April, but to be [published](#) on 21 April) to FEMA's temporary final rule prohibiting exports of certain personal protective equipment (PPE). The notice relates to both the 3 April [presidential memorandum](#) invoking emergency powers under the Defense Production Act (DPA) regarding the allocation of certain scarce or threatened health and medical resources to domestic use and a FEMA temporary final rule published in the [Federal Register](#) on 10 April 2020 and effective on 7 April 2020. The purpose of the presidential memorandum and temporary final rule is to ensure that scarce or threatened "covered materials" remain in the in the United States to aid the response to COVID-19. As of now, the types of PPE covered are primarily certain N95 and surgical masks, respirators, and surgical gloves.

The FEMA rule required U.S. Customs and Border Protection (CBP) to hold a PPE export shipment pending a FEMA determination as to its eligibility for export, and did not allow any of the PPE "covered materials" defined in the rule to leave the United States without FEMA authorization.

The 17 April FEMA notice details specific exemptions to the temporary final rule, and clarifies earlier "guidance" issued by CBP which was circulated by several trade associations. It includes a number of important clarifications and exceptions to the otherwise very broad restrictions on U.S. exports of PPE. These exemptions substantially limit the scope of the export ban by excluding exports to Canada and Mexico and providing other categorical exclusions.

Scope of FEMA rule

In the temporary rule, FEMA provided that before any shipments of the covered materials may be exported CBP would detain the shipment temporarily to permit FEMA to determine if the shipment qualifies for an exclusion. It provided that in determining whether covered materials are excluded, FEMA may consult other agencies and will consider the totality of the circumstances.

In the temporary final rule, FEMA and CBP defined "covered materials" to include the following:

- a) N95 filtering facepiece respirators, including devices that are disposable half-face-piece nonpowered 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.
- b) 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 Code of Federal Regulations 84.181.
- c) Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges.
- d) PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials.
- e) PPE gloves or surgical gloves, including those defined at 21 Code of Federal Regulations 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such gloves intended for the same purposes.

FEMA also included an exemption for "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" if "at least 80 percent of such manufacturer's domestic production of covered materials, on a per item basis, was distributed in the United States in the preceding 12 months." This exemption recognizes the potential impacts on preexisting commercial relationship within the international supply chain and the humanitarian aspect of the global pandemic response and was designed to cover the president's "deal" with 3M.

Additional FEMA exceptions

The 17 April FEMA notice exempts a number of categories of shipments from the general requirement for CBP to detain them, including:

- Exports to Canada or Mexico.*
- Exports to U.S. commonwealths and territories.
- Exports to U.S. government entities such as U.S. military bases overseas.
- Exports by U.S. government agencies.
- Exports from foreign embassies and consulates to their home countries.
- Exports by U.S. nonprofit or nongovernmental organizations for free distribution at their destination.*
- Intracompany transfers from a company's U.S. domestic facilities to affiliated foreign facilities.*
- Exports solely for assembly in medical kits and diagnostic testing kits destined for U.S. sale and delivery.*
- Sealed, sterile medical kits and diagnostic testing kits where only a portion of the kit is made up of covered materials that cannot be easily removed.
- In-transit shipments.*

The exemptions marked with an asterisk above require a "letter of attestation" to be submitted to FEMA via CBP's document imaging system and placed on file with CBP, certifying to FEMA the purpose of the shipment. The letter must include:

- A description of which exemption the exporter is claiming.
- Sufficient details regarding the shipment for CBP and FEMA to determine the shipment falls under the claimed exemption.
- A statement that the provided information is true and accurate to the best of the exporter's knowledge, and that the exporter is aware that false information is subject to prosecution under the DPA.

The letter of attestation procedure is a significant improvement over the original FEMA rule which would have required CBP to hold PPE shipments pending a FEMA determination as to their eligibility for export. While FEMA stated it would make such determinations within a reasonable time, it meant that shipments could have been tied up for long periods, and eventually seized in whole or in part for domestic use.

The new exclusions significantly narrow the potential applicability of the temporary final rule, which threatened to prevent all shipments of PPE leaving the United States. CBP issued a guidance document on Friday 9 April that set forth similar, but not identical exemptions, but according to press reports, the CBP guidance document was not meant for public release. FEMA's notice serves to clarify the scope of the temporary final rule. Since these rules are changing rapidly, companies should closely monitor CBP and FEMA guidance before shipping PPE out of the United States in order to ensure compliance with current requirements.

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