

FEMA Implementation of Allocation Order on Exports of Scarce PPE and Notice on Exemptions

FEMA published a [Temporary Final Rule \(TFR\)](#) in the *Federal Register* on Aug. 10, 2020 that allocated certain health and medical resources for domestic use to ensure needs are met for frontline healthcare workers and the American public during the COVID-19 pandemic. This TFR is an extension and modification of a TFR published on April 10, 2020 which outlined the implementation of the President's Memorandum, "[Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use.](#)"

This extension allows the TFR to remain in effect, with certain modifications, through Dec. 31, 2020. Modifications were made to the types of exports of PPE that FEMA will review and may hold for domestic use to reflect changing circumstances. For example, shipments of certain classes of surgical gowns are now covered under the TFR, and may not leave the United States without explicit approval by FEMA.

FEMA's Export Cargo Review Working Group, which includes representatives from Customs and Border Protection (CBP), the Department of State, the Department of Commerce, and the Food and Drug Administration, will continue to evaluate the PPE items included in the TFR every two weeks to review updated information about the supply and demand of covered PPE. As needed, the Export Cargo Review Working Group will submit requests to the Unified Coordination Group and White House Task Force to make modifications to the TFR.

Covered PPE Under the Allocation Order

FEMA is working in close coordination with CBP and the members of the Export Cargo Review Working Group to review shipments of the following PPE materials:

- Surgical N-95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to



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cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates;

- PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials;
- PPE nitrile gloves, specifically those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and other such nitrile gloves intended for the same purposes.
- Level 3 and 4 Surgical Gowns and Surgical Isolation Gowns that meet all the requirements in ANSI/AAMI PB70 and ASTM F2407 – 06 and are classified by Surgical Gown Barrier Performance based on AAMI PB70.

What Happens to PPE Exports Allocated in this Order

- FEMA may purchase part or all of the shipment, using a rated order under Title I of the Defense Production Act.
- FEMA may return all or part of the shipment for distribution in the domestic supply chain.
- FEMA may allow all or part of the shipment to proceed as planned for export.

The Review Process for Allocated PPE Exports

- To clarify, not every shipment of covered materials will be detained for FEMA determination, and not every shipment that is detained for FEMA determination will be prohibited from export.
- After a shipment is sent for export, CBP will conduct a preliminary review of all materials in the Automated Export System (AES), including any Letter of Attestation submitted by the shipper (if necessary). If the export clearly falls within an exemption, CBP may allow the shipment to immediately proceed to export.
- In other circumstances, CBP will send information about the export to FEMA. FEMA will review the shipment with the assistance of the Export Cargo Review Working Group, which includes representatives from CBP, the Department of State, the Department of Commerce, and the Food and Drug Administration. After FEMA makes a determination, FEMA will route the decision back to the exporter through CBP.
- FEMA is taking every action possible to minimize the delays caused by this allocation order. Once notified by CBP, from detainment to determination FEMA aims to make a decision within 72 hours of detainment.

Exemptions to PPE Exports that FEMA will Hold

In order to minimize the disruption of the supply chain and use agency resources efficiently, FEMA has established several exemptions to the allocation order. Shipments



that fall into one or more exemption may be exported automatically, subject to the caveats described at the end of this section.

The initial allocation order provided 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, so long as 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. Exporters who believe a shipment falls under this exemption should submit a Letter of Attestation (described below), describing the shipment and applicability of the exemption. This exemption is retained in the August 10th TFR.

The notification published in the Federal Register on April 17 identifies several additional exemptions, which were also retained in the August 10th TFR. Exporters wishing to submit a shipment under one of the following five exemptions must submit a letter of attestation with the shipping information entered into the AES:

- Exports of covered materials by non-profit or non-governmental organizations that are solely for donation to foreign charities or governments for free distribution (not sale) at their destination(s).
- Intracompany transfers of covered materials by U.S. companies from domestic facilities to company-owned or affiliated foreign facilities.
- Shipments of covered materials that are exported solely for assembly in medical kits and diagnostic testing kits destined for U.S. sale and delivery.
- In-Transit Merchandise: shipments in transit through the United States with a foreign shipper and consignee, including shipments temporarily entered into a warehouse or temporarily admitted to a foreign trade zone.
- Shipments for which the final destination is Canada or Mexico.

For several other exemptions, listed below, letters of attestation are not required. However, shippers may submit additional documentation if they believe it would be of assistance in helping FEMA to determine whether an exemption applies.

- Shipments to U.S. commonwealths and territories, including Guam, American Samoa, Puerto Rico, U.S. Virgin Islands, and the Commonwealth of the Northern Mariana Islands (Including minor outlying islands).
- Sealed, sterile medical kits and diagnostic testing kits where only a portion of the kit is made up of one or more covered materials that cannot be easily removed without damaging the kits.
- Declared Diplomatic shipments from foreign embassies and consulates to their home



countries. these may be shipped via intermediaries (logistics providers) but are shipped from and consigned to foreign governments

- Shipments to Overseas U.S. Military Addresses, Foreign Service Posts (e.g., diplomatic post offices), and Embassies.
- Shipments by or on behalf of the U.S. Federal Government, including its military.

In addition, if a shipper believes they have a surplus of a covered material and can demonstrate a good-faith and unsuccessful attempt to sell the material domestically, a [request must be in a Letter of Attestation](#).

The request should include:

- The material to be exported;
- The commercially reasonable efforts made to market and sell the material domestically.
- The difference, with specificity, between the domestic demand and the domestic production.
- An explanation showing that the proposed export volume will not interfere with continued satisfaction of domestic demand.

If CBP believes that an exporter is intentionally modifying its shipments to take advantage of one or more exemptions, CBP may detain a shipment and forward information about that shipment (including the basis for CBP's belief of the intentional modification) to FEMA for determination.

In addition, CBP may, in its discretion, forward on additional shipments to FEMA for consideration if the agency does not believe a shipment falls clearly into one or more exemptions.

When and How to Submit a Letter of Attestation

Letters of Attestation are only needed if the shipper plans to export one or more of the covered materials listed in the allocation order, and if this shipment falls under one of the exemptions for which a letter of attestation is required.

These letters must be submitted through the Automated Export System to Customs and Border Protection in conjunction with other export paperwork.

FEMA recommends including the following information in a Letter of Attestation:

- Description of the type and quantity of covered materials that are included in the shipment. If the shipment does not contain any of the five covered materials, then



there is no need to file the attestation letter, as the shipment falls outside the allocation order.

- A description of which exemption(s) the owner or exporter believes the shipment falls into. For a full list of the exemptions see [Notification of Exemptions](#) which was published in April to supplement the TFR.
- A brief statement describing why the claimed exemption applies.
- A brief statement describing the expected end use of the exported materials.
- A statement confirming 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, as described in the allocation order.

Relevant Authorities for Allocation Actions

Defense Production Act – Title I

The section of the DPA allows the President, and appropriately delegated agencies, to “allocate materials, services, and facilities in such manner, upon such conditions, and to such extent as he shall deem necessary or appropriate to promote the national defense” (50 U.S. Code § 4511(a)(2)).

[Executive Order 13911 - Delegating Additional Authority Under the DPA with Respect to Health and Medical Resources to Respond to the Spread of COVID-19](#)

The President Signed Executive Order 13911 on March 27, 2020. Title 4 of this Executive Order gave the Secretary of Homeland Security and the Secretary of Health and Human Services the authority to implement Title 1 of the DPA. In turn, on April 1, 2020 the Secretary of Homeland Security delegated this authority to the FEMA Administrator in Department of Homeland Security Delegation 09052 Rev 00.1, “Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency.”

[President's Memorandum - Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use](#)

In the Memorandum signed on April 3, 2020 the President noted that “it is the policy of the United States to prevent domestic brokers, distributors, and other intermediaries” from diverting five types of covered material overseas. The Memorandum directed the Secretary of Homeland Security, through the Administrator of FEMA, to “use any and all authority available under section 101 of the [DPA] to allocate to domestic use, as appropriate” the five types of covered materials provided text box.



[FEMA Temporary Final Rule - Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use](#)

On April 10, 2020 the FEMA Administrator issued and published the allocation order in the Federal Register. The allocation order allows FEMA to review shipments of PPE subject to this allotment order which include: N95 respirators, and a variety of other filtering respirators; air-purifying respirators; surgical masks; and, surgical gloves. These are the same five types of materials referenced in the President's Memorandum.

For Additional Questions

Please send an email to one of the following points of contact for any questions.

For questions for Customs and Border Protection, visit their [website](#).

For general questions about the allocation order and Notice of Exemptions in the Federal Register, send an email to FEMA National Business Emergency Operations Center, at NBEOC@max.gov.



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