



FedEx Regulatory Alerts & Updates

Regulatory Alert: FEMA Removes Certain PPE from U.S. Export Restriction

June 2, 2021

BACKGROUND

The Federal Emergency Management Agency (FEMA) published a Temporary Final Rule (TFR) on December 31, 2020. The TFR designated specific critical medical and healthcare resources for ensuring domestic uses were properly met during the COVID-19 pandemic as well as be certain that specific materials were not exported abroad. The current TFR is in effect until June 30, 2021.

WHAT HAS CHANGED?

Effective May 19, 2021, FEMA is no longer restricting the following items under the TFR:

- Industrial N95 Respirators, including devices that are currently NIOSH approved for use in healthcare settings under an Emergency Use Authorization (EUA) issued by the Food and Drug Administration (FDA);
- PPE Surgical Masks, as described by 21 CFR 878.4040, including masks that cover the user's nose and mouth providing a physical barrier to fluids and particular materials, that meet fluid barrier protection standards pursuant to: ASTM F 1862; and Class I or Class II flammability tests under CPSC CS 191-53, NFPA Standard 702-1980, or UL 2154 standards;
- Piston syringes that allow for the controlled and precise flow of liquid as described by 21 CFR 880.5860, that are compliant with ISO 7886-1:2017 and use only Current Good Manufacturing Practices (CGMP) processes; or
- Hypodermic single lumen needles that have engineered sharps injury protections as described in the Needlestick Safety and Prevention Act, Pub. L. 106-430, 114 Stat. 1901 (Nov. 6, 2000).

Q & A

Q 1 – What is the status on the other PPE that FEMA identified as scarce in the June and December 2020 TFR?

A 1 - The review and restriction from export under the TFR remains unchanged for the surgical, single-use N95 respirators, certain nitrile gloves, and certain surgical gowns.

Q 2 – Can U.S. manufacturers of the items still under restriction by FEMA use the established exemption process to export those items to foreign buyers?

A 2 – Yes. Further, manufacturers and exporters of the items that are still controlled by FEMA may request an exemption from the restrictions if they have a surplus of those specific items. The manufacturer of the items will be asked to demonstrate a good-faith and unsuccessful attempt to sell the material to the domestic market. To request this TFR export process exemption due to a surplus of materials, exporters can submit a Letter of Attestation (LOA) with the following information to docs@cbp.dhs.gov :

1. The surplus material you wish to export
2. The commercially reasonable efforts you have made to market and sell the material domestically
3. The difference, to the extent known, between the domestic demand and the domestic production
4. How the proposed export volume will not interfere with continued satisfaction of domestic demand

Q 3 – Does FEMA have a timeframe for those manufacturers to get a response on their exception request(s)?

A 3 - The submitted LOA will be reviewed. CBP and FEMA will make every effort to provide parties with a Letter of Decision within three business days. The CBP CSMS 42406108 listed in the References section provides more information about submitting the LOA for any PPE articles that customers are seeking to export.

REFERENCES

FEMA May 19 Fact Sheet:

<https://www.fema.gov/fact-sheet/information-for-exporters-with-surplus-personal-protective-equipment>

CBP CSMS 42506108:

<https://imports.cbp.gov/s/article/https-content-govdelivery-com-bulletins-gd-USDHSCBP-288977c-wgt-ref-USDHSCBP-WIDGET-2>

Regulatory Alert Update: Extension of FEMA U.S. PPE Export Review Process:

https://www.fedex.com/content/dam/fedex/us-united-states/International/images/2021/RegAlert_21-046_Update-Extension_of_FEMA_US_PPE_Export_Review_Process.pdf

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