**Analysis by Amy Porges re: Temporary FEMA regulation**

Summary:

This temporary FEMA regulation applies only to N95 respirators, similar respirators, PPE surgical masks and PPE gloves. The regulation allocates all of these materials for domestic use.

CBP will detain all export shipments of these items; FEMA will review each shipment and determine whether to return it to the shipper, allocate it to a US buyer, or allow the export of all or part of the shipment. The determination will be on a case-by-case basis taking six factors into consideration. FEMA says it will make this determination within a “reasonable time”.

FEMA has announced that shipments will be allowed if they are by or on behalf of any US manufacturer with continuous export agreements with customers abroad since at least 1/1/2020; so long as at least 80% of that US manufacturer’s US production of these materials, “on a per item basis”, has been distributed in the US in the preceding 12 months.

FEMA may agree to other such exemptions.

Details:

This is a temporary FEMA regulation to be codified at 44 CFR 328.101 – 328.104.  It applies immediately until August 8.

It applies only to five PPE items listed in §328.103:

* N95 respirators
* Other filtering facepiece respirators (N99, N100, R95, R99, R100, P95, P99, P100)
* 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;
* PPE gloves or surgical gloves, including exam gloves defined at 21 CFR 880.6250, surgical gloves (21 CFR 878.4460) “and such gloves intended for the same purpose”.

This is the same list as in the April 3 Presidential memorandum. These items are among the 15 items designated by HHS under DPA Section 102. Considering the reference to “such gloves”, it seems likely that exports of any surgical-type gloves will be detained even if the gloves do not comply with FDA regulations.

This list could be expanded later. This regulation determines that all shipments of these items are allocated for domestic use and may not be exported without explicit approval by FEMA.

CBP will inform FEMA of any intended export of these 5 items and will detain any shipment.

FEMA will then determine whether to return the goods for domestic use, issue a rated order (for delivery of the items),  or allow export of all or part of the shipment.

* FEMA will make this determination within a reasonable time of being notified of an intended shipment.
* The regulation describes a case-by-case determination by FEMA in consultation with other agencies (e.g. HHS, and others), taking into account 6 factors: (1) need to ensure that items are appropriately allocated for domestic use; (2) minimizing supply chain disruption; (3) circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns; (4) quantity and quality of the materials; (5) humanitarian considerations; (6) international relations and diplomatic considerations.

Exemption:  FEMA will generally allow exports of these items

* If a shipment is made by or on behalf of a U.S. manufacturer with continuous export agreements with customers in other countries since at least January 1, 2020
* So long as at least 80% of that US manufacturer’s US production of these materials, “on a per item basis”, was distributed in the US in the preceding 12 months.

If FEMA determines this exemption applies, the materials may be exported without further FEMA review (that is, without the case-by-case review that would otherwise be required). FEMA reserves the right to do the full review on these shipments if it deems that would be necessary or appropriate.

FEMA may establish further exemptions and announce them in the Federal Register.