

Frequently Asked Questions for New Importers of PPE and Other COVID-19-Related Products

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Due to PPE and other COVID-19 related product supply shortages within the United States, many companies and individuals without prior import experience have begun to explore sourcing critical items from outside the United States. A number of experienced importers have also shifted their product mix, and have for the first time begun importing goods that may be regulated by new agencies, such as the Food and Drug Administration (FDA). Import regulations can be complex, particularly when the product at issue is medical equipment. Under existing authorities as well as the authority of the Defense Production Act (DPA), U.S. Customs and Border Protection (CBP) and Federal Emergency Management Agency (FEMA) have recently changed the administration of certain import regulations during the COVID-19 crisis, creating further complexity.

In that context, this Frequently Asked Questions guide addresses some of the most common questions we have seen from importers of PPE – particularly new importers. The answers below provide a basic overview of some of the common issues that may arise and help importers identify potential concerns that might require further investigation or assistance from our team. Because of the complex issues that are in play in this evolving legal area, however, these questions and answers should not be taken as exhaustive advice as to the correctness of any particular transaction you may be considering.

1. How do I import Personal Protective Equipment (PPE) and other COVID-19-related merchandise from another country?

The procedures and documentation requirements when importing commercial goods from overseas are complicated, and can easily confuse the unfamiliar. If possible, the best first step is to hire a customs broker. Customs brokers are licensed companies and individuals who can act as the “official” importer – importer of record (IOR) – and assist you with importing the merchandise. There are many resources for customs brokers available for each state including those listed on the National Customs Broker and Forwarders Association of America [website](#). The broker will be able to assist you with clearing the goods through CBP as well as the other information and documentation necessary for finalizing the import filing and payment of the duties, taxes, and fees owed to CBP.

While the broker can provide experienced help to companies importing goods, the importing company (or IOR) is still required to exercise “reasonable care” even if it hires a broker. As a result, even if a broker helps you with the mechanics of importation, you should ensure that you have complete paperwork and documentation to support the entry/entry summary prepared by your broker, and that you are generally aware of the rapidly-changing importation landscape. Continue reading for a round-up of information necessary for entering the PPE into the United States, as well as up-to-date customs resources on COVID-19 relief.

2. If I am an established 501(c)(3) do I have to pay duties for the import of PPE? While there is not a general exception from import duties for charities, under the authority of 19 U.S.C. 1322(b), CBP has recently provided instruction that duty is not required for the import of PPE and other COVID-19 related articles when the recipient of the articles is a recognized tax-exempt charitable organization and the articles are used for disaster relief.

If the PPE is used for disaster relief, then CBP does not require established non-profits to pay duties on the imported PPE. Proof that the recipient of the PPE is a recognized tax-exempt charitable institution is required. Formal CBP entry documentation is not required; instead the PPE may be released by CBP from the carrier's manifest information. Note also that private groups or individuals importing the PPE must provide a letter from the charity, on the charity's letterhead, with the charity's Internal Revenue Service (IRS) number(s), stating that the non-profit accepts the imported goods and that the organization intends to donate the imported goods. CBP has provided additional information about imports for non-profits [here](#). These are new procedures, specific to the COVID-19 crisis, and therefore it is likely that at an unknown time in the future this charitable use exception will end – potentially with little or no warning. It is important that you or your customs broker reconfirm that you may enter any goods as duty free and without formal entry documents at the time your goods ship to the United States.

3. Should I be worried about purchasing unsafe or illegal PPE?

There have been reports of fly-by-night factories and distributors pumping out counterfeit or incomplete PPE and trying to cash in on the high demand and high prices. The FBI has provided additional information on red flags for fraudulent sales. These include:

- Unusual payment terms (e.g., supplier asking for up-front payments or proof of payment)
- Last-minute price changes
- Last-minute excuses for delay in shipment (e.g., claims that the equipment was seized at port or stuck in customs)
- Unexplained source of bulk supply

More information is available [here](#).

There have also been reports of fraudulent COVID-19 testing kits entering the country. More information is available [here](#).

4. Are there restrictions on the export of PPE and COVID-19-related equipment from China?

Covington has released a [client alert](#) on China's restrictions on the export of PPE and other COVID-19-related products. The alert also includes recent Food and Drug Administration (FDA) changes for US imports of PPE.

5. What information do I need to clear the PPE or other COVID-19-related merchandise through U.S. CBP?

The minimum information that CBP is requiring for COVID-19-related merchandise is available on CBP's website [here](#) and we have restated it below. Your customs broker should be able to assist with other necessary details for clearing the PPE and other COVID-19-related merchandise through customs.

To assist CBP in expediting the release of COVID-19 relief materials, please include as much data about the shipment as possible. Ideally, this will include the following:

- Shipment information: *manifest or air waybill numbers, tracking numbers, entry numbers, mode of transport information*
- Conveyance information: *carrier name, mode of transportation, flight number, vessel/voyage number, port of arrival, port of entry*
- Cargo description: *complete description of the goods being shipped*
- Country information: *country of manufacture, country of export*
- Parties involved: *names and locations of manufacturers, shippers, importers, and consignees*

It is important that you reconfirm that these requirements remain in place as of the time you import, as we expect these procedures will change in the future as the COVID-19 crisis evolves.

6. Do agencies other than Customs regulate imports?

Yes! Several government agencies are involved in the regulation of imports. Most relevant for many PPE imports is the Food & Drug Administration (FDA), as many PPE imports may be subject to FDA regulations. The FDA has been providing an updated list of resources and guidance for COVID-19 related questions and concerns [here](#) that is relevant to importers.

7. How do I declare the customs value if the PPE COVID-19-related merchandise is donated and I did not purchase it from overseas? Do I owe duty?

Particularly if the articles being imported are not specifically intended for COVID-19-related use by a 501(c)(3) charity, there will likely be a duty rate associated with many PPE products such as N95 masks. Therefore, CBP will require a “customs value” to which the duty rate is applied. CBP will still require a declared customs value for the merchandise even if the masks are being donated. Customs valuation can be complicated – while it may in many cases be the transaction value of your entry, it is not necessarily as simple as reporting the price you are paying for the goods.

In general, for donated merchandise, the merchandise cannot be appraised on the basis of “transaction value,” because the donation transaction did not involve the exchange of funds for the products. Therefore, donated goods are appraised in accordance with the remaining accepted methods of valuation, applied in sequential order of feasibility. 19 U.S.C. 1401a(a)(1). The alternative bases of appraisal, in order of precedence, are: the transaction value of identical or similar merchandise (19 U.S.C. 1401a(c)); deductive value (19 U.S.C. 1401a(d)); computed value (19 U.S.C. 1401a(e)); and the ‘fallback’ method (19 U.S.C. 1401a(f)).

In the absence of any bona fide sale, the transaction value method may not be used to determine the value of the imported merchandise. The second appraisal method in order of statutory preference is transaction value of identical and similar merchandise under section 1401a(c). This method refers to a previously accepted transaction value of identical or similar merchandise which was exported at or about the same time as the merchandise being valued. HQ 563461 (May 18, 2006). This is the most commonly used alternative valuation method in circumstances of this nature. However, valuation can be a quite complicated area, so should you need help determining the customs value, we can provide advice and further guidance. Additionally, an importer has opportunities to correct the entry or filing with CBP if the initial

declared value is incorrect, so even if you have recently made a shipment and realize you made a mistake, it may still be possible to correct that error without penalty.

8. What are my obligations if I act as the importer of record or "IOR"?

IORs have an obligation to exercise reasonable care. Generally, this means that you are responsible for accurate and complete information filed with CBP. Importers not acting with reasonable care may subject themselves to penalties based on negligence, gross negligence or fraud. There are opportunities to correct the entry or filing if you discover an error on the entry. Covington or your broker can help with understanding the various aspects of acting with reasonable care and how corrections may be made to the entry.

9. Can my broker act as the IOR for me?

Yes, however if you hire a broker to act on your behalf, then you will still be obligated to exercise reasonable care under the customs laws and regulations, and make sure that your broker is preparing the documentation correctly for you.

10. Are there any restrictions on the export of PPE from the United States?

Yes. Under a new FEMA rule, the US Government now requires FEMA to review an intended export of PPE in order to ensure that sufficient supplies remain in the United States. There are several exemptions to this rule including, but not limited to, exports to Canada and Mexico and in transit (or in bond) movements of the PPE products as well as exports by non-profits. If you intend to move PPE out of the United States, or intend to move PPE through the United States to a third country, it is critical that you understand these rules before you ship your goods. Many of these exemptions will require a letter of attestation (LOA) filed with CBP. Failure to comply with the FEMA rules can result in your goods being seized and redirected for use within the United States.

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If you have any further questions about any of the topics above, CBP has created its own portal for COVID-19 related policies and information. The portal is available [here](#).

Our team at Covington can provide support and assistance for new importers, and those navigating the changing importation landscape. For Customs questions, please contact:

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