# Media lines

The US FDA revises the eligibility criteria for some filtering facepieces

**Issue Statement:** On May 7, 2020, the United States Food and Drug Administration (US FDA) reissued the Emergency Use Authorization (EUA) for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China to remove one of the eligibility criteria: the authorization of respirators based on review of test reports from recognized independent test laboratories submitted to the US FDA by the manufacturer or importer. The FDA is taking this regulatory action because a number of these respirators failed to demonstrate a minimum particulate filtration efficiency of 95% in testing conducted at the National Institute for Occupational Safety and Health (NIOSH). Media have reported that this action reduced the number of US FDA-approved KN95 manufacturers from approximately 80 to 14.

A letter to healthcare professionals from the US FDA explained that the filtering facepieces that were withdrawn from Appendix A of the EUA (Emergency Use Authorization) and did not meet their labelled performance standard are no longer eligible and no longer authorized for marketing or distribution in the United States as filtering facepieces. The letter specifies that they may be re-labelled as face masks (instead of filtering facepieces) and authorized, if certain criteria are met for the EUA on face masks. The American decision should have an impact on filtering facepiece supply in Canada. It calls into question the quality and effectiveness of some filtering facepieces that are marketed in Canada. Health Canada is taking regulatory action. The matter should attract media attention.

The United States Centers for Disease Control and Prevention (CDC) have also expressed concern about some KN95 filtering facepieces (particularly those with loops for the ears) that make it difficult to achieve a proper fit, which is essential for their use. The N95 masks use a band (and not ear loops) and the fit and seal seem to be easier to achieve.

**Key messages:**

- Health Canada understands that health professionals who provide care to Canadians rely on personal protective equipment (PPE), including filtering facepieces, to ensure their safety. The quality, effectiveness and safety of health products are always at the forefront of Health Canada's concerns.

- On May 7, 2020, the US FDA issued revised guidelines indicating that some filtering facepieces may not provide adequate respiratory protection and sent a letter to healthcare providers, indicating that some products currently sold in the United States did not meet the expected filtration standards and were no longer authorized for marketing or distribution in the United States as filtering facepieces. Nevertheless, they can be re-labelled as face masks and authorized if certain criteria are met.

- Health Canada contacted businesses who might import and distribute some filtering facepieces in Canada, particularly KN95 filtering facepieces, which may not meet safety and effectiveness standards, to ask them to immediate stop selling these products, inform their customers, and re-label the products to indicate that even if the masks do not meet the required standards for frontline health workers, they could be used as face masks in settings where a 95 percent filtration rate is not necessary. Health Canada will take the appropriate action and inform Canadians as needed.

- Provincial and territorial health authorities and healthcare institutions were invited to review their inventory of KN95 filtering facepieces to confirm that they met Government of Canada technical specifications for COVID-19 interventions in healthcare institutions.

- This action does not apply to KN95 filtering facepieces purchased by the Government of Canada and tested by the Public Health Agency of Canada (PHAC). Before allocating personal protective equipment to the provinces and territories for frontline health workers, PHAC conducts a quality audit. For filtering facepieces, that includes a visual inspection to check for design and manufacturing flaws, and tests like those supported by the National Research Council, to confirm that they meet filtration specifications.

- The KN95 filtering facepieces distributed to the provinces and territories by PHAC meet Government of Canada technical specifications for COVID-19 interventions in health care institutions. To date, most of the products received by the Government of Canada have met the technical requirements needed in a COVID-19 healthcare context. However, PHAC's rigorous review process has revealed that 9.9 million KN95 filtering facepieces do not meet the necessary technical requirements.

- Health Canada will continue to accept masks that are equivalent to N95 masks (e.g., KN95), but will require proof of manufacturing quality and the results of tests validated by independent third-party test facilities before authorizing these products.

**Additional key messages on working with the US FDA**

- Health Canada is working closely with other regulatory organizations like the FDA, and taking comparable action as needed to help ensure the quality, effectiveness, and safety of medical devices intended for the Canadian market.

- Health Canada is actively committed and is taking urgent action on the changes made by the US FDA to its Emergency Use Authorization for made-in-China disposable filtering facepieces not approved by the NIOSH.

- The NIOSH assessment Web page includes a list of KN95 filtering facepieces manufactured in China that have been tested and the results of those tests. Health Canada will continue to take action to ensure that the products that do not meet the appropriate standards are not imported or distributed in Canada.

**Additional messages on the marketing authorization for N95 and KN95 filtering facepieces and the interim order**

- Businesses have two options for selling and importing Class I COVID-19 medical devices in the Canadian market. They can request a marketing authorization from Health Canada through the interim order for medical devices intended for COVID-19 use, or a medical device establishment licensing (MDEL).

- Health Canada reviews the scientific evidence supplied by the manufacturers through the interim order to support the safety and effectiveness of the devices before issuing authorizations for these devices.

- Current MDEL holders are advised that they are prohibited from importing or distributing filtering facepieces that failed the NIOSH tests, unless the masks are re-labelled as face

masks. New MDEL applicants will also have to ensure that they do not import or distribute filtering facepieces that do not meet the applicable filtration standards.

- N95 and KN95 filtering facepieces and their equivalents are Class I medical devices. However, to allow Health Canada to conduct a scientific review before the marketing authorization of these devices, manufacturers are encouraged to submit applications under the interim order rather than through the MDEL regulatory path.

**Additional messages on the testing and status of KN95 filtering facepieces**

- In Canada, manufacturers of Class I medical devices that include N95 and KN95 filtering facepieces once had a choice of two regulatory paths: a medical device establishment licensing or authorization under the interim order.

- Although Health Canada continues to accept masks that are equivalent to the N95 masks certified by the NIOSH (e.g., KN95, FFP2), it will continue to ask for proof of manufacturing quality and validated test results. Under the interim order, Health Canada can also impose a condition of certification of validated test results by independent third-party test facilities.

**Additional messages for healthcare institutions**

- Health Canada recommends that health professionals test filtering facepieces for proper fit before using them, even if they differ from N95 respiratory masks.

- Health Canada is committed to ensuring that medical devices made available to Canadians meet safety and effectiveness standards. Health Canada monitors potential issues in the Canadian market and will take the necessary action.

**Additional messages on compliance and enforcement options**

- There are a number of possible compliance and enforcement options to correct non-compliance or to mitigate the risk for Canadians, including site visits, recalls, public communications, and product seizures.

- Health Canada adopts a risk-based approach that takes account of the circumstances of each case to protect the health and safety of Canadians.

- The main objective of Health Canada's approach to compliance and enforcement consists of managing risks for Canadians by using the most appropriate level of intervention.

- In this case, if some KN95 filtering facepieces do not meet the required standards for frontline health workers, they could still be used as face masks in settings where the 95 percent filtration standards are not necessary. Consequently, recalling the filtering facepieces in question and re-labelling them as face masks addresses the risk.

**Additional messages on Canada's PPE and medical supplies**

- Health workers need medical masks, including surgical masks, masks for medical procedures, and filtering facepieces, such as the N95 filtering facepiece. It is extremely important to maintain the supply of medical masks where they are needed.

- The Government of Canada strives to ensure that health workers have the PPE and the medical supplies they need. To do this, we are working with the provinces and territories in the area of bulk procurement, we are strengthening national production capacity and we are identifying alternatives and possible ways to extend the life of these products.

- Canada is working to quickly allocate PPE and medical supplies to the provinces and territories based on an approach agreed upon by the federal, provincial and territorial health ministers.

- The PPE and medical supplies received by the Government of Canada, whether purchased in Canada or abroad, are checked by PHAC to ensure that they meet Government of Canada technical specifications in a COVID-19 healthcare context. The procedure is the same for donated material.

- If the PHAC cannot account for the quality of the products, they will not be allocated to the provinces and territories for frontline healthcare interventions.

- The audit process varies according to the medical device. For example, KN95 filtering facepieces, as an accepted alternative to N95 filtering facepieces, are inspected visually to detect potential design and manufacturing flaws, and tested to confirm that they meet the specifications for filtering facepieces.

- To date, the majority of the products received by the Government of Canada meet the technical requirements needed in a COVID-19 healthcare context. However, PHAC's rigorous review processes have revealed that 9.9 million Kn95 filtering facepieces do not meet the necessary technical requirements.

**Questions and answers:**

**Q1. Since there are fewer accredited manufacturers of N95 filtering facepieces in the United States, what will be the impact on the Canadian supply of N95 filtering facepieces?**

Health Canada understands that the health professionals who provide care to Canadians rely on their personal protective equipment, including filtering facepieces, to ensure their safety. The quality, effectiveness and safety of health products are always at the forefront of Health Canada's concerns.

The Government of Canada will continue to work to ensure an adequate supply of N95 and equivalent filtering facepieces to meet the needs of the health system. This is achieved through collaborative wholesale procurement with the provinces and territories, increasing national production capacity, and identifying potential options and extending product lifecycles.

**Q2. I am a health professional. What should I do with my KN95 mask? Who do I contact to find out if it has been tested and has passed the test?**

Health professionals can consult the NIOSH assessment Web page to find out if their made-in-China KN95 filtering facepieces have been tested, and review the test results. Filtering facepieces that did not meet the stated performance standard must not be used by frontline health workers to protect themselves against COVID-19.

The filtering facepieces distributed to the provinces and territories by PHAC meet Government of Canada technical specifications for COVID-19 interventions in healthcare institutions.

**Q3. How is Health Canada adjusting its standards or its review process in light of the US FDA announcement?**

Health Canada will invite importers, distributors, and manufacturers of N95 filtering facepieces or equivalents (e.g., KN95) to submit their COVID product applications through the interim order process.

Health Canada will continue to accept alternative standards that are equivalent to the N95 standard, but will request proof of manufacturing quality and validated test results conducted by independent test facilities in order to authorize them.

**Q4. What is Health Canada doing to mitigate the shortage of medical devices resulting from COVID-19?**

Health Canada is actively monitoring the potential impact of the COVID-19 pandemic on the supply of medical devices in Canada. The Department is adopting a three-pronged approach: monitoring, multiparty collaboration, and efforts aimed at guaranteeing the supply of required health products.

Health Canada continues to involve the medical device industry and the provinces and territories to watch for any signs of supply disruption in Canada.

Manufacturers and importers are now required to inform Health Canada about shortages of medical devices considered critical for COVID-19. In addition, manufacturers and importers are encouraged to identify any shortages of other medical devices on a voluntary basis.

Manufacturers and importers must inform Health Canada within five days of becoming aware of a real or anticipated shortage. This provision is similar to what is already required of pharmaceutical companies. Public identification of shortages helps the healthcare system prepare for supply disruptions.

Health Canada has contacted all holders of medical device establishment licences and all holders of medical device establishment licences in Canada to remind them of their obligation to identify any anticipated or actual shortage of essential medical devices that appear on the List of medical instruments related to COVID-19, which currently includes the following devices:

- Masks (for example, surgical, procedural, or medical)
- N95 filtering facepieces for medical use
- Face shields
- Gowns
- Ventilators (including bi-level expiratory positive airway pressure ventilation devices)

The Department is also accelerating the issuing of medical device establishment licences to increase the number of institutions that can import and distribute critically needed medical devices.

The Department will continue to follow the situation closely and will take all necessary action together with businesses, provinces and territories and other stakeholders to ensure an ongoing supply of medical devices in Canada.

**Q5. What do the different letters and numbers of the face mask types refer to? What is an N95 as compared to a KP95 or a KN95?**

N95 and KN95 are considered equivalent designations for filtering facepieces that must meet filtration standards of 95 percent.

The letter N means not resistant to oil, while the letter P indicates that the mask is resistant to oil. N95 filtering facepieces meet the American standard established by the NIOSH, and the KP95 and KN95 filtering facepieces meet an equivalent Chinese standard.

The Government of Canada has developed detailed specifications for PPE, such as N95 disposable filtering facepieces. Additional information on the products and services required and the corresponding specifications is available on Health Canada's website.