

January 14, 2021

Notice to Stakeholders re: Interim Measure for Exceptional Release of Hard Surface Disinfectants or Hand Sanitizers

On March 18, 2020, Health Canada introduced an interim measure for the exceptional release of hard surface disinfectants and hand sanitizers to expedite access to products that may not fully meet regulatory requirements under the *Food and Drugs Act*. This interim measure enabled Health Canada to facilitate the availability of supplies of hard surface disinfectants and hand sanitizers for Canadians.

Since the interim measure was established, over 650 hand sanitizers and hard surface disinfectants have met the criteria for importation and sale and over 3,500 new alcohol-based hand sanitizers have been licensed. A market analysis of the supply and demand of alcohol-based hand sanitizers, undertaken by Health Canada, determined that there is now sufficient domestic manufacturing capacity to meet the current demand.

Given this information, the pressing public health need that informed the interim approach for hand sanitizers no longer applies. As such, as of January 15, 2021, Health Canada will stop accepting notification forms for hand sanitizers under the interim measure pathway.

What does this mean?

For Current Hand Sanitizer Products Listed on the [Online List of Disinfectants and Hand Sanitizers Accepted Under COVID-19 Interim Measure](#):

The analysis mentioned above was used as an indicator of capacity provided by currently licensed sites and domestic manufacturing capacity. Products previously accepted under the interim measure will continue to be allowed to be imported and/or sold; however, no new applications for hand sanitizers will be accepted post- January 15, 2021.

Notification forms for hand sanitizer products that contain complete and accurate information and submitted prior to January 15, 2021, will continue to be processed.

No changes are being made to the interim measure process for exceptional release regarding hard surface disinfectants at this time. Health Canada will continue to accept notification forms for hard surface disinfectants under this interim measure, until the supply of these products stabilizes.

Health Canada will provide advance notice to companies that received a confirmation email of acceptance through the interim measure, outlining the process when the interim measure expires. As such, no action is required for companies who submit complete applications before January 15, 2021.

For Future Notifications for Hand Sanitizers through this Interim Measure:

As the assessment of the Canadian market determined that the domestic production capacity of alcohol-based hand sanitizers is currently stable, as of January 15, 2021, Health Canada will cease accepting new applications for hand sanitizers through this interim measure. From this date, Health Canada will revert to the standard, pre-COVID-19, regulatory process for the manufacturing and/or importation of these products.

Companies seeking to import, fabricate (manufacture), package or label hand sanitizer products, should pursue the [relevant licences for these products and related establishments](#).

Notification forms for hard surface disinfectants will continue to be accepted under this interim measure until the regular supply of these products stabilizes. Health Canada will monitor the supply and demand of hard surface disinfectant and hand sanitizer products in Canada and will communicate all changes regarding the market landscape, as necessary.

Health Canada is committed to supporting the health and safety of all Canadians as we combat COVID-19.