

Lockington, Elliott (SPAC/PSPC)

From: Gordon2, Travis (HC/SC)
Sent: March 24, 2020 9:36 AM
To: Chan, Marco (IC)
Cc: Murdock, Kelly (SPAC/PSPC); Caira, Celine (IC)
Subject: RE: Clarification on sanitizer/disinfectant approval

Your read is correct. I have also been engaged by Spirits Canada and offered them the same guidance.

If they are importing product, then only an EDL or an SL would be required. If they are manufacturing, they would also have to get product approval (this will be incredibly fast if they have experience with the formulation). For businesses producing liquor, food, we are also allowing attestation that they meet food-related GMPs into order to ensure their facility can produce a clean product.

In terms of getting an EDL or SL, it really just an attestation that they meet the requirements as outlined by HC. Best if they connect with HC for guidance on needs specific to their establishment.

The value in the additional flexibility really comes in the ability to attest to meeting requirements and to expedited review times. But we do still need to make sure the product is safe.

For the clarifications: 1) there is no difference between consumer or institutional use. The product is fundamentally the same so the process is the same. 2) The requirements for business apply whether payment is received or whether it is free.

In terms of distillers, those manufacturing hand sanitizer without a licence actually aren't doing so legally. But we are not rolling hard on compliance and enforcement in this area right now, for obvious reasons, unless a safety risk presents.

TG

From: Chan, Marco (IC) <marco.chan@canada.ca>
Sent: 2020-03-24 9:26 AM
To: Gordon2, Travis (HC/SC) <travis.gordon2@canada.ca>
Cc: Murdock, Kelly (SPAC/PSPC) <kelly.murdock@canada.ca>; Caira, Celine (IC) <celine.caira@canada.ca>
Subject: Clarification on sanitizer/disinfectant approval

Hi Travis,

Quick question on hand sanitizer and disinfectants. We're getting a lot of questions and I want to tell them the right info so we reduce churn and questions...

Am I understanding correctly from [this guidance](#) that businesses looking to sell hand sanitizers (NHP or non-prescription drug) and disinfectants (non-prescription drug) need approval from Health Canada for the product and a Drug Establishment Licence (DEL) or Site Licence (SL). Therefore, they should contact hc.covid19healthproducts-produitsdesante.sc@canada.ca to understand/begin process?

Two further clarifications:

- Does this initial step differ by those looking to produce for consumers (hand sanitizers that may be NHP or NPD) vs. for institutional use (e.g., hospitals, NPD)? I figure the approval process will differ slightly – more checking if we should refer them to the same email/contact to understand/begin.
- Does this initial step or approval requirements differ for businesses that are giving away (for free, not selling) hand sanitizers? (e.g., many distillers want to give away, like this well-known [Toronto example](#))

Like I said, lots of interest in this from industrial chemical producers, Spirits Canada, and smaller producers, so just want to be correct off the bat and save us all work down the line. I know there's some ingredient shortages, bottle shortages, we may not end up wanting to procure all the offers, so we're happy to discuss these fronts too.

Cheers,
Marco

Marco Chan

Conseiller en politiques
Cabinet du ministre de l'Innovation, des Sciences et de l'Industrie
marco.chan@canada.ca / Tél. : 819-744-0194 / ATS : 1-866-694-8389

Policy Advisor
Office of the Minister of Innovation, Science and Industry
marco.chan@canada.ca / Tel: 819-744-0194 / TTY: 1-866-694-8389