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THOUGHT LEADERSHIP

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Keeping it Clean: Responding to Increased Demand for Hand Sanitizers

Product Compliance During and After the Pandemic

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The COVID-19 outbreak has sent countries all over the world scrambling to control the spread of the disease. In addition to social distancing mandates and shelter-in-place edicts, people are being told to wash their hands vigorously and to use anti-microbial hand sanitizer as often as a few times every hour when soap and water are unavailable. The inevitable outcome has been soaring demand for anti-microbial hand sanitizer.

To fill this need, many health authorities around the globe have temporarily modified regulatory requirements specific to hand sanitizers, creating the opportunity for new entrants into this market in both the near and long term. A number of manufacturers, small and large, have expressed interest in producing ingredients or formulating final hand sanitizer products aimed at both individual consumers and medical professionals.

In the Unites States, the FDA has issued several temporary guidelines giving wide latitude to companies that want to make ingredients for hand sanitizers or produce the entire product themselves. For those companies interested in doing so, the FDA has offered guidance with formulation options, as well as labeling to be used on the hand sanitizer packaging.

The temporary guidelines also include a roadmap to facilitate rapid FDA registration and listing. For those who want to distill alcohol for hand sanitizers, but who are not registered drug manufacturers with the FDA, the product firm must be registered, and the alcohol must be a listed drug. For those who want to manufacture the finished final product, but who are not currently licensed or registered as over-the-counter drug manufacturers, the firm must also register with the FDA and their products must be listed.

In Europe, some countries have already streamlined the processes for registering new anti-microbial hand sanitizers and handling requests to extend existing registrations to products not originally intended to protect a user from viruses like SARS-CoV-2 (the virus that causes COVID-19). In Austria and Denmark, all that continues to be required is a notification to the government, while governments with more stringent certification regimes have since modified their processes in response to the pandemic. For example, Switzerland previously required tests related to efficacy, as well as the results of toxicological analyses. Swiss authorities have since determined that for products meeting certain thresholds, such as 70–80% ethanol content, no tests are necessary to prove their effectiveness at fighting bacteria, fungus, mycobacteria, or viruses.

The public would benefit if other countries followed Switzerland's lead and moved to accelerate products onto the market without the need to complete and submit lengthy applications and abundant data. When products are based on the standard World Health Organization formula, it should be a quick and simple process to get those products into the hands of consumers and medical professionals.

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The various regulatory accommodations being made in the broader battle against coronavirus are likely temporary, so producers must consider what the post-crisis environment will look like. New manufacturers of hand sanitizer ingredients and the finished product, in particular, must pay attention.

For companies in the United States who want to enter the market after this public health emergency is over, it is important for them to remember that the historical FDA rules must always be followed and to consider this in their business model.

For those operating in Europe, they should recognize that there is no harmonized registration procedure at present for ethanol, which is yet to be approved under the Biocidal Products Regulation (BPR) that creates a standard across the continent and the United Kingdom. Under national rules, the exact process to be followed varies according to the country concerned. As a consequence, there is wide variation in data requirements, approval lead times, and regulatory costs. For propan-1-ol and propan-2-ol, the BPR requirements apply throughout Europe. In both cases, the current exceptions are only temporary, and if companies want to continue to place products on the market, they will need to follow the standard procedures.

How Exponent Can Help

Exponent's multi-disciplinary team of chemical regulation and product safety experts has broad-based experience under regulatory regimes and in markets around the world. We can help clients ensure their products comply with temporary guidelines aimed at fighting the current global health crisis and that they still comply when pre-crisis guidelines return in a post-crisis world.

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