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US federal agencies actively monitoring and enforcing coronavirus-related compliance

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Fraud has increased dramatically during the pandemic as companies try to profit off of the skyrocketing demand for medical and cleaning supplies. Due to years of just-in-time supply chains that valued speed over inventory, as well as decades of globalization that led corporate executives to seek cheaper materials and labor outside of the developed world, medical and disinfectant supply chains are spread thin and have proven too inflexible to effectively meet demand.

The United States Environmental Protection Agency (EPA) keeps a list of all of the disinfectants that meet EPA criteria for use against SARS-CoV-2 (COVID-19), known as List N.[1] This list is updated frequently and is the best resource for determining whether a product that claims to be effective against COVID-19 actually is.

The EPA announced a loosening of rules[2] in March regarding how companies obtain certain inert ingredients in order to help ease supply chain challenges, while also keeping List N up to date. But the chemicals and disinfectant supply chains still rely on outsourced raw materials arriving on ship to meet demand, so lead times are incredibly long. The difficulties sourcing result in higher prices and even more demand. Companies such as Estée Lauder have retooled previously closed factories[3] while others have attempted to diversify their supply chains by seeking out new third-party vendors and suppliers.[4]

Adding new capacity to supply chains is difficult even in normal times, but during a pandemic, when customers are demanding tons of hand sanitizer in weeks but such quantities can only arrive in months, the onboarding process can result in problems. Companies unable to practice proper due diligence or perform on-site audits may find themselves with product that runs afoul of U.S. Food and Drug Administration (FDA) or EPA compliance requirements.[5]

Furthermore, the Temporary Enforcement Policy[6] the EPA had in place since March is now no longer in effect. The policy considered the difficulties of managing compliance during the pandemic—as well as worker shortages at the agency itself—and appeared to loosen some enforcement policies. That is no longer the case as of Aug. 31.

As *RSCC* reported[7] in July:

"The FDA requires foreign establishments that manufacture medical devices for importation into the U.S. to comply with applicable U.S. regulations before, during, and after their importation."

Companies are urged to follow current good manufacturing practices, consult the lists kept by both the EPA and FDA as well as make use of any applicable emergency authorizations.

EPA guidance

A compliance advisory document released in May, "What You Need to Know Regarding Products Making Claims to Kill the Coronavirus Causing COVID-19,"[8] contains brief explanations of some of the more prevalent risks companies face, as well as links to additional resources.

The advisory references List N for disinfectants as well as the Federal Insecticide, Fungicide, and Rodenticide Act, which governs certain pesticidal devices, including those that claim to kill the coronavirus. The EPA does not review pesticidal devices and therefore cannot attest to their efficacy. These devices are also not on List N.

The advisory also states that the EPA is working with the U.S. Department of Justice and other relevant authorities to track down complaints and pursue enforcement against products making false and misleading claims regarding the coronavirus. A case in point would be the warning letters sent out by the FDA to companies that have made false claims, manufactured fake goods or engaged in illegal adulteration.

Be on the safe side

An example *RSCC* listed in August[9] demonstrates how fine the line is between making fraudulent claims and trying to sell a product. The FDA sent a warning letter out to a Maryland-based company that claimed its products containing CBD may be able to fight COVID-19. The FDA listed the following as an example of a statement that was misleading and a possible violation of the Federal Food, Drug, and Cosmetic Act:

> 'We are getting a lot of questions about whether CBD (Hemp Extract) can help with the Coronavirus (COVID-19). The short answer is YES, it certainly can help. Now, let's be clear, it is not seen as a cure, but CBD has properties (anti-bacterial, anti-viral, and anti-inflammatory) that can aid with symptoms and help a person stay healthy to fight off illness.'

Companies should assume that the standard enforcement capabilities of the EPA, the FDA and the Department of Justice regarding compliance with applicable laws, due diligence in regard to third-party vendors and due diligence regarding misleading statements are in full effect. As the EPA memo stated, "After this policy is no longer in effect, the EPA expects full compliance going forward."[10]

Takeaways

- The EPA and other federal agencies are actively monitoring coronavirus-related supply chains.
- Enforcement capabilities are currently in full effect; the temporary loosening of enforcement announced by the EPA in March is no longer in effect.

1 "List N: Disinfectants for Use Against SARS-CoV-2 (COVID-19)," Pesticide Registration, United States Environmental Protection Agency, last updated September 10, 2020, https://bit.ly/2Rc1qZt.
2 U.S. Environmental Protection Agency, Chemical Safety and Pollution Prevention (OCSPP), "EPA Continues Efforts to Help Increase the Availability of Disinfectant Products for Use Against the Novel Coronavirus," news release, March 26, 2020, https://bit.ly/32f7IO0.
3 Leslie P. Norton, "Thousands of U.S. Factories May Be Able to Be Retooled to Fight Coronavirus, According to a New Survey," *Barron's*, April 2, 2020, https://bit.ly/2ZruAYP.
4 Karen Kroll, "Product pivoting: Compliance issues to consider," *Report on Supply Chain Compliance* 3, no. 14 (July 23, 2020), https://bit.ly/2XcEWea.
5 Sascha Matuszak, "US Food and Drug Administration closely monitoring COVID-19-related fraud," *Report on*

Supply Chain Compliance 3, no. 15, (August 6, 2020), https://bit.ly/35vrYNk.
6 U.S. Environmental Protection Agency, "COVID-19 Enforcement and Compliance Resources," last accessed September 10, 2020, https://bit.ly/3iinDk9.
7 Karen Kroll, "Product pivoting: Compliance issues to consider."
8 U.S. Environmental Protection Agency, "What You Need to Know Regarding Products Making Claims to Kill the *Coronavirus* Causing COVID-19," compliance advisory, May 2020, https://bit.ly/35q2OzF.
9 Sascha Matuszak, "US Food and Drug Administration closely monitoring COVID-19-related fraud."
10 U.S. Environmental Protection Agency, "COVID-19 Implications for EPA's Enforcement and Compliance Assurance Program," memorandum, March 26, 2020, https://bit.ly/2GT9YCz.