

Supply and Preparedness Planning for Hand and Surface Hygiene

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A better tomorrow starts today

We all believe this, yet making these words a reality is often easier said than done. This report should be a resource to support supply contingency planning for critical public health and hygiene products, helping you and your agency stay prepared to perform your organizational mission at every moment.

PART 1 reflects the crash course we each received when the balance of supply and demand for critical public health products was unexpectedly disrupted, including a recap of the FDA's temporary guidance on hand sanitizer and why that's important.

PART 2 takes a deeper look at relevant regulations, sharing why some options, like bulk, refillable solutions, fall short and even introduce incremental risk.

PART 3 shares five useful tactics for creating a comprehensive and pragmatic contingency supply plan for health and hygiene products.

PART 4 covers the benefits of choosing the right manufacturer to bolster your plan.

We now live in a world that was given a very stark reminder about the virtues of planning ahead, a lesson nobody wants to learn again. We hope this resource is an aid to the invaluable work you're engaged in to ensure proper preparedness for government agencies for the future, whatever it may hold. To share feedback or start a conversation, please contact me at edwardsd@gojo.com.

Stay well,

Dan

Dan Edwards
Vice President & General Manager, Public Sector
GOJO Industries, Inc.



Lessons from COVID

Changing the way we think about preparedness

In 2020, COVID-19 put supply chains to the test in alarming ways. Households and businesses were met with empty retail shelves – no sign of toilet paper, gloves, masks, disinfecting wipes, and hand sanitizer in sight.

This sudden and urgent shift in supply and demand naturally put added pressure on government contingency stockpiles. If fortunate enough to have reserves, officials were forced to divvy supplies based on answers to nearly impossible questions. Should schools close? Do hospitals have the supplies they need? What businesses should be considered essential? How quickly can we open testing sites?

Meanwhile, basic flow of supplies struggled to bounce back as manufacturing facilities were hit by COVID-19 outbreaks, forcing lines to shut down for weeks at a time.

FDA Temporary Guidance on Hand Sanitizer

Hand sanitizer is an FDA-regulated, over-the-counter drug. Therefore, to help officials meet extraordinary demand, the FDA issued temporary guidance in March 2020 that loosened some of the regulations typically required of hand sanitizer compounding as well as for the alcohol used in hand sanitizer.

Temporary guidance included:

- Simplified hand sanitizer formula approved by the World Health Organization (WHO).
- Simple documentation of key steps and controls to assure each batch matches the formula developed for the drug product.
- Allowing use of the most accurate method of analysis available at the site for verification of alcohol content.

hand sanitizer

World Health Organization

FDA





This was an important step in getting essential products to life-saving operations, businesses, schools, and homes.

However, some unintentional negative effects soon followed, including:

- Dangerous hand sanitizer formulations entered the market.
- Bulk-sized jugs and refillable open containers became popular, introducing potential for human error and contamination.
- People overpurchased the hand sanitizers produced under the temporary guidance.

First of all, as government executives are more aware than most, there is a reason FDA regulations are typically so stringent. Many non-drug manufacturers were simply not up to the challenge and introduced potentially dangerous or risky hand sanitizers into the market. The FDA has a warning list of more than 350 hand sanitizers that do not meet safety standards, temporary or otherwise. The list includes hand sanitizers that have been tested by the FDA and found to contain unacceptable levels of methanol, 1-propanol, benzene, acetaldehyde, or acetal; products that do not have enough of the active ingredient; labels with false, misleading, or unproven claims; and more.

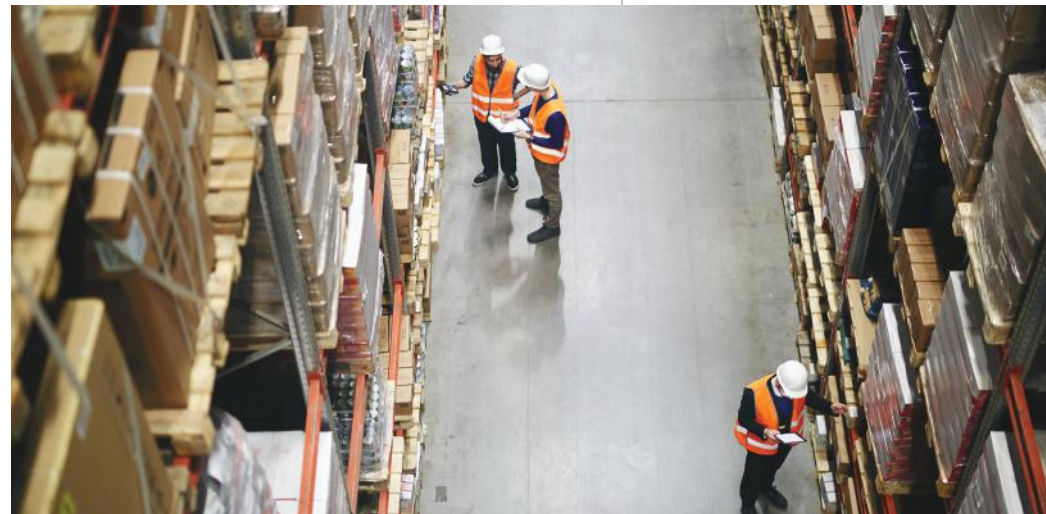
Second, temporary guidance, by definition, must come to an end. As of March 31, 2022, hand sanitizers made under the temporary guidance were no longer allowed to be sold or distributed by manufacturers.

Many organizations overpurchased these products, leading to a glut of lower quality hand sanitizers in reserves that don't have important label information necessary for keeping stockpiles up to date.

The Future

While it is impressive to note all the ways the public and private sectors came together to meet critical needs, it is clear there are lessons we must take into consideration.

Fortifying contingency plans to be better prepared for future challenges must be a top priority. This guide will show you simple ways to check current inventories and make smart choices that will support public health initiatives.



Regulations & Risks

Why proven hygiene solutions are critical for government contingency stockpiles

With the recovery of hand and surface hygiene supply chains, now is the ideal time for government agencies to check inventories and consider the standards by which they build contingency stockpiles. The following are important regulations and risks associated with hand hygiene and surface disinfection products.

DID YOU KNOW?

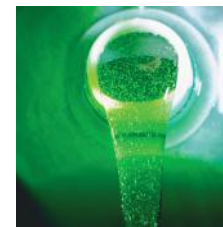
Expiration date is critically important for alcohol-based hand sanitizer. It indicates how long the sanitizer will remain stable and effective since its active ingredient evaporates over time.

Hand Hygiene Products

The withdrawal of FDA temporary guidance for hand sanitizer kicked off a mandate that non-drug manufacturers stop selling and distributing hand sanitizer produced under this guidance as of March 31, 2022. But there still may be a significant amount of this product in inventories and stockpiles.

There are key ways to immediately tell if hand sanitizer was produced by a non-drug manufacturer (see reference 1A).

FDA regulations apply both to formulations and to packaging. So looking for this information in inventories not only helps to identify lower quality hand sanitizer – but also is vital to properly keeping up government stockpiles. Without lot numbers to track recalls or expiration dates, keeping this hand sanitizer in reserves can put people at risk.



The Bad News of Bulk

The sudden need to obtain mass quantities of hand sanitizer and soap had many turning to the convenience of bulk-sized jugs and refillable open containers. While buying bulk might make sense for toilet paper in a wholesale club, there are real risks to packaging and refilling hand hygiene products by this method.

A bulk hand sanitizer or soap dispenser is easy to identify by the door on top to pour in new product and a reservoir rather than a separate, replaceable refill container.

For hand sanitizer, the CDC has noted caution about such dispensers,² and testing by independent lab Valisure LLC revealed significant health risks.³ A study by the University of Arizona also found that 25% of refillable bulk soap dispensers contain unsafe levels of bacterial contamination.

Further, since it is an FDA regulated drug, mixing hand sanitizers is illegal, but this is an incredibly easy mistake to make with open refillable dispensers.

There are 4 key areas negatively impacted by bulk dispensing systems:

- Efficacy & Safety
- Contamination
- Improper Dose of Hand Sanitizer
- Experience

1A

Evaluate hand sanitizer supplies for the following:

Short Ingredient List

If the product has only alcohol, glycerin, hydrogen peroxide, and water, and is a thin liquid, then it likely was created as part of the temporary guidance.

No Ingredient List

Past Expiration Date

Does Not Have a Lot Code

Bad Odor and/or Irritates Skin

Mislabeled or Not in Original Labeled Container

Flecks, Discoloration, or Unusual Consistency

Is it on the FDA Warning List?¹

inadvertent contamination

Efficacy & Safety

The CDC cautions that adding product to open hand sanitizer containers (known as “topping off”) may cause an imbalance in the active ingredient due to alcohol evaporation, potentially reducing effectiveness.²

**30%
OF BULK
HAND
SANITIZER
SAMPLES**

had potentially dangerous chemicals, like acetal (respiratory irritant) and acetaldehyde (potential carcinogen in a test²).

One out of every four refillable bulk soap dispensers are contaminated with unsafe levels of bacteria, leaving hands with up to 25 times more germs after washing than before.

Contamination

Topping off hand sanitizer can cause inadvertent contamination according to the CDC,² including:

- Ingredients combining in unknown measure.
- Mixing new with potentially expired product.

Open refillable soap and sanitizer containers can be tampered with or exposed to foreign objects, like insects, hair, and dust.

Improper Dose of Hand Sanitizer

When a hand sanitizer dispenser is incorrectly refilled, it can impact how many pumps are necessary to kill germs because:

- The dispenser might not be calibrated for that product.
- The wrong product could jam the pump.
- Mixed products can separate and become less effective.

Bad Experience

There's no easier way to discourage good hand hygiene than a bad experience. Human error introduces the potential for real problems in bulk dispensers.

- The CDC cautions mixing hand sanitizers can cause skin irritation.²
- Mixing can also cause watery or sticky product.

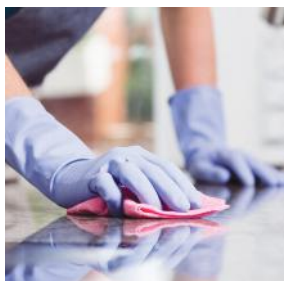
If your government agency relies on bulk hand sanitizer or soap and open refillable containers, now is the right time to check inventories and stock up on more sanitary options with sealed refills to protect safety and effectiveness when it matters most.



the **PURELL**[®]
Brand difference

PURELL SANITARY SEALED™ refills are factory sealed to help lock out germs and help prevent tampering, contamination, and human error.

Surface Products



Because surface disinfecting products are not intended for use on the human body, they do not fall under FDA guidance. Instead, the Environmental Protection Agency (EPA) monitors these goods.

While the quality of surface products did not come into question in the same way as hand sanitizer, there are ongoing questions officials should always ask about the surface disinfectants they purchase.

For example, many surface disinfecting products have precautionary statements on their labels instructing the use of gloves and other PPE. Many are not approved for food-contact surfaces and require an extra step of rinsing the surface with water after using the product.

This adds an extra level of training required for maintenance teams and staff who have to use these products. Now consider issuing these products to critical government employees during emergency times when that training is inconvenient or not likely to happen. Lastly, think how precious gloves become during a pandemic. Officials want PPE to be allocated to people managing infectious diseases – not an everyday surface product.

EPA Safety Ratings

The EPA groups surface disinfecting products into four categories based on a series of toxicity tests. Per EPA.gov, the following signal words on labels help to indicate in which category a product falls:

Toxicity Category I	DANGER
Toxicity Category II	WARNING
Toxicity Category III	CAUTION
Toxicity Category IV	NO PRECAUTIONARY STATEMENTS

Sticking with Category IV products ensures end users will be able to use the products easily, efficiently, and without added concerns.

the **PURELL**[®]
Brand difference

PURELL[®] Surface Disinfecting Wipes and Spray
have an EPA Category IV Toxicity Rating –
the highest safety rating possible – with no
precautionary statements.

EPA

Right Products. Right Places.

Essential checklists for preparedness planning



GOJO has 5 Ohio-based manufacturing facilities

GOJO Industries is located in Akron, Ohio, and has invested heavily in expanded capacity for PURELL products to help preparedness efforts.

It's never too early to review or develop a supply contingency plan. When unexpected circumstances occur, having a robust supply of hand hygiene and surface disinfection supplies that are proven and trusted is your first line of defense.

5 Tactics for Creating a Comprehensive and Effective Contingency Hygiene Supply Plan

1. Use nationally recognized brands that produce effective products and meet high safety standards.
2. Select businesses that maintain domestic manufacturing capable of supporting large, ongoing supply requirements.
3. Encourage good hygiene practices by choosing products people like to use and see in use.
4. Consult a trusted expert or well-known organization.
5. Consider proper placement for products based on need and traffic patterns.

The **PURELL** PROMISE™

Every bottle of PURELL® Hand Sanitizer is made of only high-quality ingredients, is manufactured according to strict FDA safety and regulatory standards, and has passed rigorous testing to ensure it is safe and effective.

Planning Your Supply Solution

Hand Sanitizer

What to Consider

- FDA recommends at least 60% ethyl alcohol.
- Packages include drug facts, lot number, expiration date, and manufacturer contact information.

What to Avoid

- Products on FDA warning list (www.fda.gov/handsanitizerlist).
- Unlabeled dispensers or packages that make it difficult to track during recall.
- Bad odors, or skin irritants, or thin consistency that could drip on floors.
- Refillable open containers.





Hand Soap

What to Consider

- Ingredients that promote skin health and moisturization, like glycerin, ceramides, and jojoba oil.
- Designed to be "mild" or "suitable for sensitive skin" (fragrance-free, dye-free, soothing).
- Options for foam formulas – especially near handwashing sinks.

What to Avoid

- Harsh ingredients, such as Sodium Dodecyl (lauryl) Sulfate (SDS).
- Formulas that do not lather or rinse off well.
- Refillable open containers.

Surface Disinfectant Spray and Wipes



What to Consider

- Active ingredient list on front panel.
- Listed on EPA List N (COVID-19).
- Won't damage surfaces or equipment. Compatible on hard and soft surfaces.
- Sustainable formulas or packaging options (EPA Design for the Environment [DfE] Certification, etc.).
- Can be used on food-contact surfaces without rinsing.

What to Avoid

- Bottles that are not labeled per EPA regulations (packages must include product name, directions for use, EPA registration number, precautionary statements).
- Precautionary statements – Harmful fumes or requirement to wear PPE and wash hands after use.
- Long contact-time requirements (greater than 2 minutes is not feasible or efficient).

Ensure Proper Placement of Products

When developing your program, think about when and where people need to clean their hands and disinfect surfaces. The PURELL® brand has developed S.E.T. Principles that reinforce hygiene best practices.

STAND OUT: Make the product accessible and easy to spot when there are competing distractions.

EASY: Place products in the natural flow of traffic to increase likelihood of use.

TIMELY: Make products available when they're needed – exits and entrances, point of medical care, food prep counters, eating areas, bathrooms, any gathering spaces.

The PURELL® brand helps officials do all of the above, so they can rebuild a reliable supply contingency plan now and be prepared for the unexpected in the future.



the PURELL® Brand difference

PURELL® Surface Spray and Wipes are ready to use on food-contact surfaces without an extra rinse step. They have the highest EPA safety rating and are made with no harsh chemicals.

Knowing Who to Trust

How to succeed with formulation, supply security, sustainability, and diversity

After assessing necessary ingredients and product standards, it's time to also consider the product manufacturer. Are they capable of supporting the volume you require? Do they have a robust supply chain? Do they manufacture with sustainable and diverse operations and values, not only to the standard required by procurement policies and regulations, but to the degree that people increasingly demand?

GOJO possesses all these qualities and more so that you have a supplier that can partner with you on the execution of a contingency plan end-to-end. And as the makers of PURELL® products, GOJO is a leader in innovation with a portfolio that meets all your hygiene needs in one stop.

GOJO is ready to help government officials prepare contingency stockpiles today thanks to unprecedented investments, including:

- Bringing forward 10 years of capital expenditure.
- Adding new facilities to our U.S.-based operations.
- Introducing new high-speed filling lines.
- Increasing capacity now, and in the future.
- Securing a dedicated source of high-quality alcohol (ethanol).

All of this was done while remaining dedicated to The GOJO Purpose of:

Saving Lives and
Making Life Better
Through Well-Being Solutions



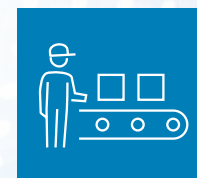
WBENC-certified Women's Business Enterprise, which helps businesses meet aggressive diverse spend goals.



Cradle to Cradle Certified® Gold achieved for many key products in our portfolio, with a Platinum Material Health rating.



2018 Award Finalist for Ethical Corporation Innovation of the Year & Responsible Business of the Year.



Doubled manufacturing space and tripled production capacity, including bringing many critical functions in house.

GOJO and the PURELL Brand

GOJO is a purpose-driven family enterprise that has been making well-being a priority through science and innovation for more than 75 years. A true American dream story, the enterprise began from humble origins in the heart of Akron, Ohio, and has expanded to include five Ohio-based manufacturing facilities. Since then, the PURELL® brand has become known as a badge of trust, one immediately recognized in hospitals, restaurants, schools, businesses, airports, entertainment venues, and homes worldwide.

As a result, having PURELL products on hand, ready in times of need, lets you take credit for all the things you've done to prioritize the well-being of your agency and those you serve. With PURELL products, agencies get the strength needed to kill germs, and for once it's without needing to make compromises.

Formulation Counts

PURELL hand hygiene and surface formulations are the result of decades of scientific innovation, with strong, differentiated offerings that no one else can provide.

The PURELL brand offers a trifecta of Powerful Efficacy and Proven Quality from a Trusted Brand.

While others may match one or two of these, none have the true, worry-free disinfection and the peace of mind that comes with the PURELL name.

Backed by rigorous testing and third-party certifications, these uncompromising hand sanitizers, hand soaps, and surface disinfection products eliminate having to use multiple suppliers or choose between strength, trust, and quality.

Environmental Sustainability

The PURELL brand is always pushing for new opportunities to develop products that include plant-based ingredients and are free of dyes, preservatives, and harsh chemicals.

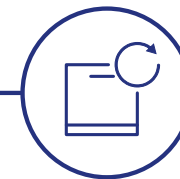
These efforts are backed by the Cradle to Cradle Certified® Product Standard, which recognizes products that are safe, circular, and responsibly made. Many of our formulations have achieved Gold status, and we received Platinum Certification in the Material Health category.

We've worked hard to meet the strict requirements necessary for certification



Safe

Products are safe for people and the planet



Circular

Products and design processes support a circular economy



Responsibly Made

Products promote healthy social and environmental practices

More than 330 global SKUs connected to PURELL brand products are Cradle to Cradle Certified® Gold. These include the first Gold-level hand sanitizers in the world to achieve this certification, helping you meet your goals for social and environmental sustainability.



Sustainable Values

Beyond our clean chemistry, we're supporting sustainability in our daily practices. In 2021, 95% of our hand sanitizers formulas are made with 50% renewable energy. This year, we're aiming even higher.

Every decision we make is guided by four sustainable value strategies:

- Innovate to Create Sustainable Value
- Elevate Public Health and Well-Being
- Steward a Thriving Environment
- Foster a Culture of Sustainable Value



**INNOVATE TO
CREATE
SUSTAINABLE
VALUE**



**ELEVATE
PUBLIC HEALTH
AND
WELL-BEING**



**STEWARD A
THRIVING
ENVIRONMENT**



**FOSTER A
CULTURE OF
SUSTAINABLE
VALUE**

Supplier Diversity

GOJO is certified as a Women's Business Enterprise (WBE) by the Women's Business Enterprise National Council (WBENC), the largest certifier of women's business enterprises in the U.S. and a leading advocate for women business owners, leaders, and entrepreneurs.

GOJO is led by Marcella Kanfer Rolnick, third generation of family leadership and Executive Chair, and Carey Jaros, President and CEO. Their leadership is guided by GOJO's core values, and this certification helps government agencies and businesses make progress toward goals for supplier diversity.



Want to learn more?

Visit GOJO.com or contact your supplier of hand hygiene and surface disinfection products today to learn more about the trailblazing innovations that can help government officials prepare for unprecedented times.

1. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use>
2. <https://www.cdc.gov/handhygiene/providers/index.html>
3. Manuel CS, Yeomans DJ, Williams JA, Fricker C, Kucera K, Light D, et al. (2022) Presence of unsafe chemical impurities, accelerated evaporation of alcohol, and lack of key labeling requirements are risks and concerns for some alcohol-based hand sanitizers and dispenser practices during the COVID-19 pandemic. PLoS ONE 17(3): e0265519. <https://doi.org/10.1371/journal.pone.0265519>
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