

Overcoming the Regulatory Hurdles for the Production of Hand Sanitizer for Public Health Protection: The UK and US Academic Perspective

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ABSTRACT: The COVID-19 pandemic has led to an acute shortage of hand sanitizer, which is crucial to keeping people safe and to preventing the spread of the SARS-CoV-2 virus. However, universities across the world have used their expertise to help to meet urgent demand from public bodies and the emergency services for supplies of safe and effective sanitizer. We explore here the experience of the University of Bristol, UK, in negotiating the regulatory demands and logistical challenges facing its own sanitizer production efforts. We also reflect on the different regulatory situation for US colleagues pursuing similar activities, and we share our advice for other universities wishing to follow a similar path.

KEYWORDS: WHO, hand sanitizer, COVID-19, public health, health & safety, regulatory compliance

The COVID-19 pandemic represents the greatest public health crisis in living memory. It has outstripped rapidly the capacity of governments and regulators to respond, meaning that individuals and organizations have increasingly stepped up to develop new ways of doing what needs to be done. In this Commentary, we explore how university chemistry departments in the UK and the US have used their skills, expertise, and facilities to help bridge the short-term gap between supply and demand for hand sanitizer for frontline workers and vulnerable people. Focusing on the University of Bristol, UK—which is now making hundreds of liters of healthcare-grade hand sanitizer a week for donation to local organizations—we explore in particular the regulatory issues facing this endeavor and how they have been overcome. We also consider the different regulatory issues facing US universities engaged in similar activities and how, based on our experiences, these can be addressed.

The clearest and most consistent message throughout the pandemic has been the need for people to wash their hands regularly and thoroughly. While soap and water are best, hand sanitizer is a good substitute in high-flow areas or when suitable hand-washing facilities are not available. The resulting demand for hand sanitizer has, however, rapidly outstripped the capacity of existing sources of supply. This has led to concern from hospitals, schools, care homes, emergency services, and other employers of essential workers that they will not be able to keep their people safe. By mid-March, within the UK, retail prices for genuine hand sanitizer were soaring, and existing stocks were being prioritized for use by the emergency services, meaning that, for other highly vulnerable organizations such as care

homes, high-quality and effective hand sanitizer was proving impossible to obtain.

It was at this stage that my colleague, bioengineer Adam Perriman, and I realized that, with the facilities of a leading university chemistry department at our disposal, we were in a position to help. Adam had identified a World Health Organization (WHO) formula for local production of hand sanitizer based on isopropanol (there is also an ethanol-based variant),¹ which we made that weekend at home and tested on our spouses and neighbors. In addition to the alcohol, all the formula required was diluted hydrogen peroxide, glycerol, and water. With this initial 2 L batch a success, we returned to our laboratories and made a further 50 L, which we distributed among colleagues in our respective departments. At this point, it was observed in a university-wide online staff briefing that other university chemistry departments were already making hand sanitizer, with the query as to whether colleagues at Bristol could do something similar. I contacted Hugh Brady, the University President, on 20th March, explained what we had done to date, and asked if he would like us to explore the possibility of scaling up our activities. His answer: (an emphatic) yes.

Our first step was to secure continued access to the now locked-down chemistry building, which necessitated liaison with

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our faculty administration and Health and Safety Group, together with the preparation of chemistry- and COVID-based risk assessments. We identified the currently vacant undergraduate laboratories as a suitable and safe place for our work. They offered plenty of space for social distancing among our growing team, an elevator connection to our stores department, and all the glassware and equipment that we needed. We were also able to draw on our smaller-scale trials to develop a simple step-by-step protocol that made the production of hand sanitizer as easy—and as fool-proof—as possible.

***Making Hand Sanitizer: The US Perspective.** When the US began to experience a shortage of hand sanitizer in early March, many academics and university officials recognized that they needed to act quickly to protect their campus communities. Prior to the announcement of campus-wide shutdowns and research scale-backs, it was unclear whether or not academic laboratories would continue functioning as usual. Instead of waiting for clarity, individual research laboratories began to acquire the materials necessary to produce their own sanitizers, hoping to keep their groups up and running if needs be. Once shutdowns began, many universities started producing hand sanitizer locally. While some operated at a small-scale as a way to simply protect their essential employees, others ran large-scale productions to allow for donations to the surrounding communities as well. Though chemists seem to have spearheaded the majority of these initiatives, other scientists, health and safety specialists, and university officials from all different backgrounds also played essential roles in supporting and, in some cases, leading the hand sanitizer operations.*

However, before we could start to produce and distribute sanitizer across the University and in the wider Bristol community, there were a number of important regulatory hurdles that we needed to overcome. The University's legal and insurance teams were, rightly, concerned about matters of liability if we started providing hand sanitizer to local bodies via the city's distribution network. Furthermore, while National Health Service (NHS) hospitals and healthcare providers were actively seeking supplies of hand sanitizer, they could only accept sanitizer that conformed to certain, very stringent requirements. Specifically, it had to have an alcohol content in excess of 70%.

Working closely with the University's legal team, we also determined that, because it is classified within the UK as a biocide, the WHO isopropanol formulation requires prior product authorization from the Health and Safety Executive² (HSE). However, the HSE has the authority, in cases of threats to public health, to offer derogation from the usual approval requirements.^{3–11} Furthermore, because the University does not pay duties on its supplies of absolute or denatured alcohol, and we were already licensed to purchase limited amounts of both, we needed to secure authorization from Her Majesty's Revenue and Customs¹² (HMRC) to change the use to which we were about to put them and to lift the cap on how much we could purchase.

Because the sanitizer we were making used a formula issued by the WHO, the University's legal team was satisfied that, provided we could meet the various external regulatory requirements, we would be covered from a liability and insurance point of view. Furthermore, because the WHO formula had a final alcohol concentration of 75%, it was more than sufficient to meet NHS requirements. The NHS also required, though, that our sanitizer had product authorization—

or the appropriate derogation—from the HSE. However, the necessary approvals from the HSE^{8,9} and HMRC¹³ were to prove a little more difficult to secure.

To obtain approval from HMRC for the “change of use” of our duty-free and denatured alcohol (for which we had existing licenses to purchase limited amounts as part of our research and teaching activity),^{14,15} we simply wrote to them explaining what we wanted to do. Due to the impact of the pandemic, HMRC was operating at significantly reduced capacity—and had limited resources devoted to this aspect of its activities anyway—so was slow to respond. However, after a few web chats and telephone calls to follow up our request, approvals were duly granted. While we recognize that HMRC was simply trying to apply its approval processes rigorously, so as to weed out fraudulent applications or “snake oil” operations, the delay was frustrating. We were, in fact, almost at the point of just going ahead and “asking for forgiveness” at a later date. We note that HMRC has since produced formal guidance for organizations wishing to produce hand sanitizer and has set up streamlined approval procedures, which will hopefully make it easier for such organizations to obtain the necessary permissions.¹³

In order to secure derogation from the HSE's normal product authorization requirements, we needed to demonstrate that we were sourcing our isopropanol from a European Chemicals Agency¹⁶ (ECHA) approved manufacturer. This involved demonstrating that, in addition to a purity greater than 99%, the material contained “no more than 2 ppm benzene”. Our initial application for derogation failed because, while our certificate of analysis confirmed the required overall purity level, it did not mention explicitly the benzene content. We then contacted Sigma-Aldrich (now Merck Life Science), our isopropanol supplier, who quickly offered to liaise with the HSE on our behalf. They clearly have much more experience than us in working with regulators. They were also very keen to help and ultimately helped us to secure the necessary derogation by sharing with the HSE commercially sensitive information relating to the manufacture of the isopropanol. The HSE has issued specific guidance for organizations wishing to manufacture WHO-specification sanitizer, explaining how they can secure the necessary derogation.^{8,9}

We agreed with the HSE that, as an interim measure while we awaited the outcome of their discussions with Sigma-Aldrich, we could determine the ppm level of benzene in high-purity material either in-house (using gas chromatography mass spectrometry) or by using a third-party analyst. We now test routinely the benzene content of isopropanol that we use, and detecting levels below 2 ppm is well within our capabilities. The HSE confirmed that they were content with either of these approaches, which provided us with considerable peace of mind at that stage, as well as the ability to meet what was becoming an increasingly pressing need. The message we got from our dealings with HSE colleagues was that they were seeking actively to find a way to provide our hand sanitizer with the necessary derogation, so that we could start distributing it locally. It helped, I think, that we were from an internationally recognized university, which could be relied upon to deliver to a very high standard. Our tenacity at this stage instilled, we suspect, a certain level of confidence regarding what we wanted to do and our ability to do it properly.

Regulatory Requirements: The US Perspective. In the US, hand sanitizers are regulated as over-the-counter drugs by the US Food and Drug Administration (FDA).^{17,18} In early March, hand sanitizer was becoming exceedingly difficult (if not impossible) to find due to the COVID-19 public health emergency. By late March, in an attempt to help meet the increased demand, the FDA had published three temporary policies regarding the production of hand sanitizers. While clearly intended to assist individuals eager to help in the midst of the pandemic, the policies, titled “Guidance for Industry”,¹⁹ have been a source of confusion for many across the US largely due to the vague and ambiguous language used.

Only a couple of weeks earlier, the US Department of Health and Human Services (HHS); a department in which the FDA is just one division) invoked the Public Readiness and Emergency Preparedness (PREP) Act, granting certain entities immunity from liability when taking the measures necessary to respond to a public health emergency.²⁰ This seemed to further confusion, as receiving multiple communications from different parts of the same department regarding liability made it unclear who exactly had the final say. On numerous occasions, ethanol producers have experienced a relaxation of regulations only to see them tighten again soon after, causing enough confusion that even lawmakers are asking for clarity. US universities have shared in this confusion as it is unclear where the university systems fall regarding the HHS PREP Act and FDA guidelines, and whether or not universities can supply their hospital systems with hand sanitizer without formally registering as a manufacturer.

While industrial guidelines seem to be a work in progress, the FDA guidelines for “compounders” (i.e., licensed pharmacists and physicians) looking to produce hand sanitizer are more clear-cut, allowing pharmacists, physicians, and anyone working under their supervision to produce hand sanitizer without registering with the FDA.²¹ For this reason, many universities have been able to bypass the ambiguity of the industrial regulations by working with their pharmacy or medical schools. As for universities where such a partnership is not an option, communication with other institutions has been vital in making game-time decisions as approved reagents become scarce and problems arise that the FDA has not yet addressed.

With the necessary approvals in place, it was all systems go. At which point it became all about the logistics. We needed to obtain significant volumes of alcohol, glycerol, and hydrogen peroxide. We also needed to locate suitable—and a sufficient number of—dispensers, which were flying off the shelves. Our procurement and stores teams got in touch with a range of suppliers, whose first question was invariably “Are you authorized to make this?” It was here that our HSE and HMRC letters of approval came into their own, as they got us onto our suppliers’ priority lists and helped us to secure the supplies we needed. It was some weeks before it felt as though we were in “steady state” in terms of the necessary materials, component ingredients, and dispensers. However, we are now ordering 1000 L of isopropanol at a time, for example, as well as batches of 500–1500 (usually 500 mL) pump dispensers.

Our search for supplies also led us to issue university-wide requests for available solvent, glycerol, and peroxide, containers to mix them in, and all sorts of other odds and ends. These requests proved very fruitful and turned our work into a genuine

team effort. We struck a deal with Bristol Waste, the City Council’s refuse collection company, that they would help out with raw materials in return for a share of the resulting sanitizer. Another local university donated their solvent stock to us, and we provided them with sanitizer for their residential and security teams. The University’s print services team designed and printed thousands of HSE compliant (and very nice) labels. A friend of mine who runs a wine distribution company donated sturdy boxes, which proved essential to the distribution of the end product. In addition, a feature about our work on the local television news resulted in further offers of support, especially with distribution.

The bulk of our distribution to date has been through Bristol’s Local Resilience Forum (LRF), which brings together representatives of local government organizations, National Health Service bodies, the emergency services, and other agencies to coordinate their response to large-scale emergency situations. This took the burden of distribution off our shoulders and ensured that the sanitizer we produced got to where it was most needed. We should note at this point that, while the City Council is providing some of the isopropanol we required, we are manufacturing and distributing the resulting hand sanitizer at no charge. We are grateful to the University for providing an amount of funding—and, of course, our time and the use of its facilities—that allows us to do this.

At the time of writing, we are shipping 300 L a week of sanitizer to the LRF for onward distribution across the city and beyond. Using an efficient 10 L batch process, which allows us to make 500 L of sanitizer in 2 h with three people, we have so far converted three 1000 L “intermediate bulk containers” of isopropanol into sanitizer for specific users, and we have supplied sanitizer directly to teams across the University (mainly our residences, security, and information technology teams) as well as to a small number of other organizations. We are now supporting the University as it seeks to reopen its campus, working closely with the estates team to determine how we can best deploy hand sanitizer across research-intensive buildings (including Chemistry) safely, pragmatically, and effectively. We have also just started to make a gel variant of the sanitizer, simply because that is easier to manage than the liquid WHO formulation. It does, however, raise new issues around scale-up and HSE product approval and associated derogation that will have to be addressed.

Current Situation: The US Perspective. For now, the supply chains have caught up, allowing for universities to acquire industrially produced hand sanitizer. However, several challenges remain. For example, with the sharp increase in the number of companies trying their hand at producing hand sanitizer, not every product marketed as such is effective or even safe for use on skin. Whereas almost all manufacturers have labeled their product as a “WHO-recommended formula”, upon closer inspection, some products have been found to contain additional ingredients such as quaternary ammonium compounds, while other products lack alcohol altogether. A number of US universities have already begun a phased reopening, but as the rest of the country starts to reopen as well, there is a great deal of concern regarding whether or not supply chains will be able to keep up long-term. While the FDA continues to monitor the situation closely and update their guidelines accordingly, the regulations regarding the production of hand sanitizer (and how they affect US universities specifically) remain unclear.

On reflection, going from producing a couple of bottles of hand sanitizer at home to manufacturing it on a quasi-industrial scale has been a roller coaster ride for all of us. However, everyone with whom we have come into contact—from university colleagues to regulators to a whole range of suppliers—has been helpful, supportive, and keen for us to succeed. Having been contacted by various other universities seeking our advice on how to initiate their own hand sanitizer operations, we worked with the Royal Society of Chemistry to prepare and distribute a “how-to” guide to getting HSE and HMRC approval.²² Lessons have been learnt,²³ and there will be more to follow as clearly pitfalls do remain.^{24,25} We are also mindful of how we can develop our activities and increase further the scale on which we are operating. We set out to cover a short-term gap in supply. That initial gap may well have closed, but now, as workplaces open up, the demand for hand sanitizer is going to increase dramatically, and we are now well-positioned to support the University, and the wider community, in continuing to combat the spread of the virus and as we seek to reopen our activities after the lockdown within what remains a fluid and uncertain environment.²⁶

Timothy Gallagher

KEY LEARNING POINTS

Some key learning points are as follows:

- Regulators have a language of their own. Learn it. Understand it. And use it when communicating with them.
- Establish your credibility. There are a lot of “snake oil salespeople” and fraudsters out there, but universities are well-trusted and ideally placed to make a genuine difference.
- Be persistent (and polite) when dealing with people internally and externally. They want you to succeed and are willing to go the extra mile to help you, but they may need to be convinced. And they, too, will be juggling many things.
- Be open and honest about what you are doing and why you are doing it. It has helped that we are not seeking to profit financially from our activities.
- Establish the facts about what is required. Do not cut corners. Do not guess or make assumptions. If you are not sure, ask.
- Ask for support when you need it. You will be surprised by the number of people and organizations who want—and are able—to help you.

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Notes

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- (1) Detailed WHO formulations are available, see: *Guide to Local Production*. https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf (accessed 28 June 2020). Minimum purities are defined and while certain components, such as the humectant, can be varied, only glycerol is specified in these formulations.
- (2) HSE operate the UK’s workplace regulatory environment analogous to the US Occupational Safety and Health Administration (OSHA).
- (3) Understanding the HSE regulatory environment around biocides was key, see: *Biocides—HSE*. <https://www.hse.gov.uk/biocides/index.htm> (accessed 28 June 2020).
- (4) For other key aspects of this regulatory environment, see: *The EU Biocides Regulation 528/2012 (EU BPR)*. <https://www.hse.gov.uk/biocides/eu-bpr/index.htm> (accessed 28 June 2020).
- (5) For other key aspects of this regulatory environment, see: *The 22 Product Types (‘PTs’) of the Biocidal Products Regulation (528/2012)*. <https://www.hse.gov.uk/biocides/eu-bpr/product-types.htm> (accessed 28 June 2020).
- (6) For other key aspects of this regulatory environment, see: *Product Authorisation under EU Biocides Regulations (EU BPR)*. <https://www.hse.gov.uk/biocides/eu-bpr/product-authorisation-overview.htm> (accessed 28 June 2020).
- (7) Specific Covid-19 relevant advice was also produced, see: *Hand sanitiser products and surface disinfectants during the coronavirus outbreak—use, manufacture and supply*. <https://www.hse.gov.uk/news/hand-sanitiser-manufacture-supply-coronavirus.htm> (accessed 28 June 2020).
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- (9) For other key aspects of these temporary measures, see: *Manufacture and supply of biocidal hand sanitiser products during the coronavirus outbreak*. <https://www.hse.gov.uk/coronavirus/hand-sanitiser/hand-sanitiser-manufacture-supply.htm> (accessed 28 June 2020).
- (10) The Biocide Product Regulated (BPR) environment enforced by HSE refers only to the isopropanol and not the ethanol variant of the WHO formulation.
- (11) HSE derogation is associated with a formal requirement to inform the UK’s National Poisons Information Service. *The National Poisons Information Service (NPIS)*. <https://www.hse.gov.uk/biocides/eu-bpr/informing-npis.htm> (accessed 28 June 2020).
- (12) HMRC has a wider taxation remit (analogous to the US Internal Revenue Service) but regulates alcohol (approval of licenses to buy and use; application of duty tax) in a similar way to the US Alcohol and Tobacco Tax and Trade Bureau (TTB; part of the US Department of the Treasury).
- (13) HMRC Covid-19 relevant information, see: *Producing hand sanitiser and gel for coronavirus (COVID-19)*. <https://www.gov.uk/>

guidance/producing-hand-sanitiser-and-gel-for-coronavirus-covid-19 (accessed 28 June 2020).

(14) In the UK, many distilleries (often gin producers) who held existing licenses for duty-free alcohol (pure ethanol) turned production to hand sanitizer. However, it is important to appreciate the distinction between duty-free alcohol and industrial denatured alcohol (IDA) which is typically < 96% ethanol plus a denaturing agent to render the product “undrinkable. Details of IDA variants are available at the following: *Previously approved uses for industrial denatured alcohol*. <https://www.gov.uk/government/publications/excise-notice-473-production-distribution-and-use-of-denatured-alcohol/excise-notice-473-production-distribution-and-use-of-denatured-alcohol#section17> (accessed 28 June 2020).

(15) For uses of and restrictions associated with Duty-Free Spirit, see: *Excise Notice 47: duty free spirits - use in manufacture or for medical or scientific purposes*. <https://www.gov.uk/government/publications/excise-notice-47-duty-free-spirits-use-in-manufacture-or-for-medical-or-scientific-purposes/excise-notice-47-duty-free-spirits-use-in-manufacture-or-for-medical-or-scientific-purposes> (accessed 28 June 2020).

(16) Although the UK has left the European Union, EU Biocides Regulation 528/2012 (EU BPR) remain in force. ECHA, which is an agency of the European Union, provides the regulatory environment associated with the management of chemicals. For information relating to biocide regulation, see: *Information on biocides*. <https://echa.europa.eu/information-on-chemicals/active-substance-suppliers> (accessed 28 June 2020).

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(21) Specific advice associated with the compounding of hand sanitizer, see: *Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency*. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-temporary-compounding-certain-alcohol-based-hand-sanitizer-products-during-public-health> (accessed 1 July 2020).

(22) A guide was requested by the Heads of Chemistry forum, which is administered by the Royal Society of Chemistry, and circulated to UK chemistry departmental chairs. The guide has not yet been published more widely.

(23) A very timely (and currently freely accessible) review provides an overview of the range of products and associated formulations that are currently available. Berardi, A.; Perinelli, D. R.; Merchant, H. A.; Bisharat, L.; Basheti, I. A.; Bonacucina, G.; Cespi, M.; Palmieri, G. F. Hand sanitisers amid CoViD-19: A critical review of alcohol-based products on the market and formulation approaches to respond to increasing demand. *Int. J. Pharm.* **2020**, *584*, 119431–119445.

(24) On June 19 2020, FDA issued an advice warning against use of hand sanitizer containing large quantities of methanol, the hazards of which have been documented [25], see: *FDA advises consumers not to use hand sanitizer products manufactured by Eskbiochem*. <https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-consumers-not-use-hand-sanitizer-products-manufactured-eskbiochem> (accessed 28 June 2020).

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(26) The HSE derogation for WHO Formulation 2 (isopropanol) was issued to the University of Bristol on 2 April 2020 and was valid for 180 days (to 25 September 2020). On 25 June, that was automatically extended to 30 March 2022 on the basis of a request made by HSE to the European Commission. Extensions beyond that are, however, subject to the producer applying for and being granted full BPR product authorization, a process that will involve a fee of \$25,000–\$30,000.