in focus

Household biocides

Striking a balance between claims and regulations in the COVID-19 world

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a **science group** company

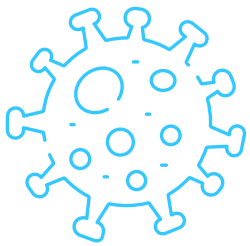
The COVID-19 pandemic has driven a global surge in demand for household biocides, creating new opportunities for manufacturers. TSG Consulting conducted extensive research to establish what consumers want from these products and whether they have confidence in product claims. This report considers the findings alongside strict regulatory requirements governing how these products are positioned and marketed around the world.

Balancing consumer expectations with regulatory requirements

As the events of the COVID-19 pandemic unfolded in 2020, consumer sales of household biocides for disinfecting surfaces skyrocketed. As demand increased, stores around the world struggled to maintain an adequate supply of products such as antibacterial spray, disinfectant and wipes. Today, while the initial panic buying of household biocides has subsided, demand remains high.

Here at TSG Consulting, we've noted several COVID-19-driven trends amongst manufacturers of household biocides. Many of our clients are considering how they might expand product claims, for instance to convey stronger antimicrobial properties or long-lasting efficacy. Harmonization of labeling is another priority; the pandemic spotlighted the advantages of having one product primed for deployment in multiple markets according to demand. In the US, there's also been an uplift of manufacturer interest in equipment and devices that can be used to disinfect personal items and larger areas in the home.

Any household biocide is subject to regulatory considerations surrounding its formulation (i.e. active substances), efficacy claims, intended use, and labeling. This is a complex matter which varies greatly across, and even within, target markets. Understanding this is vital. However, it's also important to appreciate consumers' expectations, behaviors, and demands in relation to these products.



As the COVID-19 pandemic enters its second year, people are coming to accept that it is a long-term problem which we need to learn to live with. Household biocide manufacturers that strike an effective balance between consumer expectations and regulatory requirements are set to thrive. Furthermore, new products that hinder the survival of SARS-CoV-2, the virus that causes COVID-19, could play a major role enabling populations to return to more normal ways of living.

Terminology

For consistency, this report standardizes on the terms 'biocide' and 'biocidal' to describe household products used for disinfectant purposes, as per the European Union definition:

Biocidal products are used with the intent to destroy, deter, render harmless, prevent the action of, or control, harmful organisms.[1]

In this report, the focus will be on organisms that are harmful to humans.

Consumer research

To better understand consumer perceptions in relation to product claims for household biocides, we commissioned extensive research between 21 December 2020 and 8 January 2021.

We surveyed representative samples of adults in Canada, France, Germany, Spain, the UK and USA to ascertain which products they had purchased due to COVID-19. Then we elicited their thoughts on areas such as efficacy, claims, and labeling.

A total of 8,828 adults completed the online interview. Findings and statistics referenced in this report relate to the full sample, across all six countries, unless otherwise stated. The figures have been weighted and are representative of all country adults (aged 18+).

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TSG's consumer research reveals that 79% of adults in Canada, France, Germany, Spain, the UK and USA have purchased at least one biocidal or protective product for personal use in response to COVID-19. Traditional household biocides such as antibacterial sprays and wipes were one of the most popular categories (Figure 1). However, we also covered the use of equipment and devices which disinfect or sanitize large and inaccessible areas or clean items which cannot be wetted. This report looks at both categories in terms of consumer attitudes and associated regulatory considerations related to efficacy and safety.

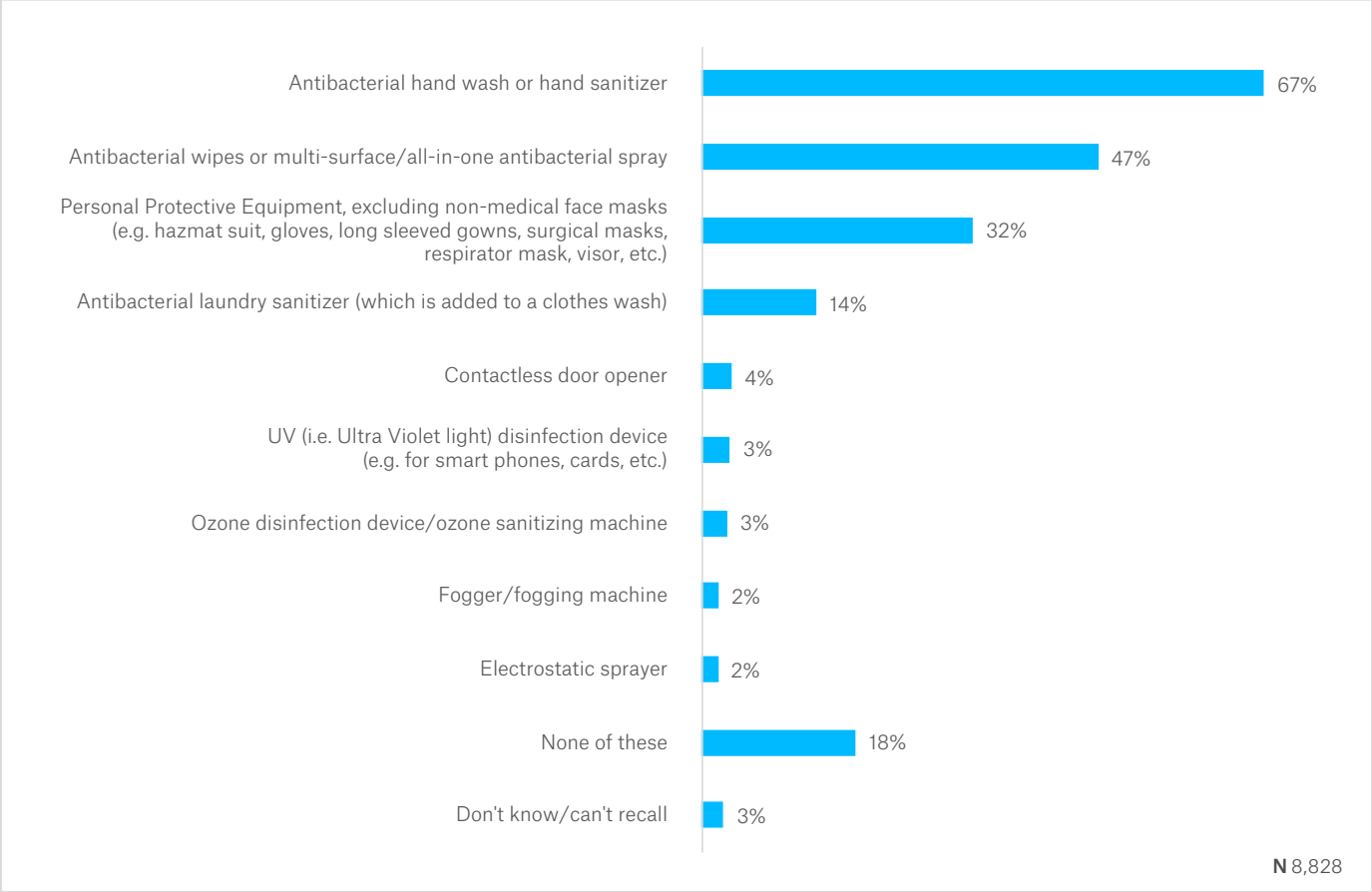


Figure 1: Findings related to the question "Thinking about since the start of the coronavirus (COVID-19) outbreak in your country... Which, if any, of the following products have you purchased for personal use because of coronavirus (COVID-19)? (Please select all that apply)"

Traditional biocidal products

Based on average research findings across the six countries, almost half of all adults (47%) have purchased antibacterial wipes and multi-surface sprays in response to the pandemic. As Figure 2 illustrates, the figure rose to 60% in the UK, 58% in the US and 54% in Canada. Germany had the lowest rate of purchase, at 34%.

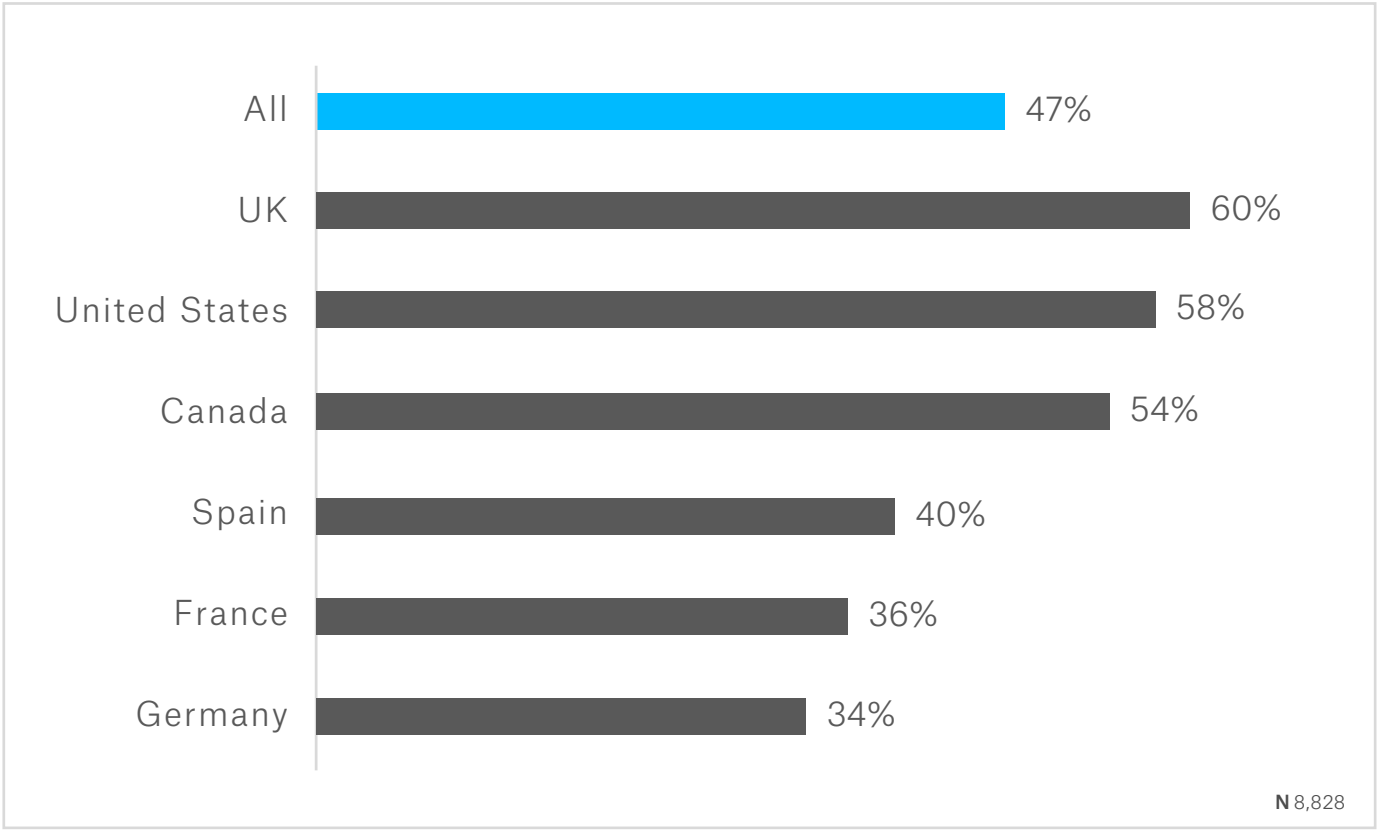
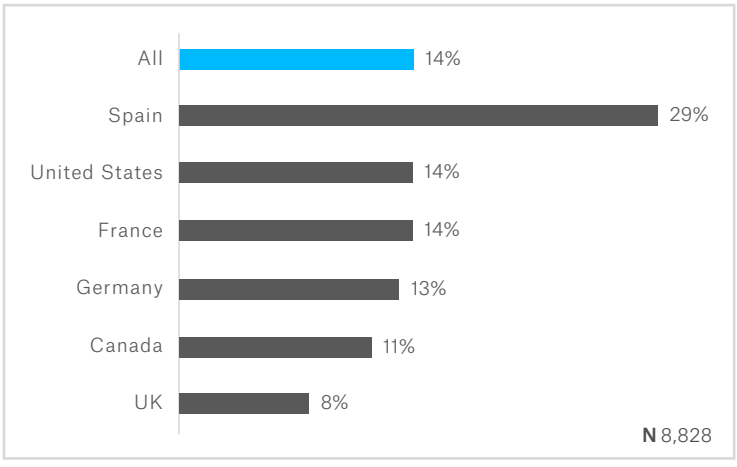
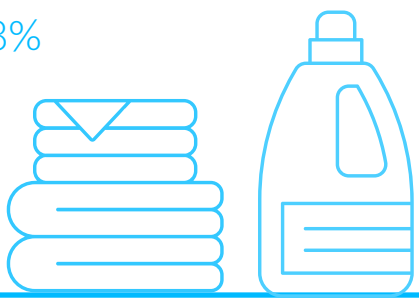


Figure 2: Percentage of consumers purchasing antibacterial wipes or multi-surface/all-in-one antibacterial spray

With demand for these products likely to remain high, new market entrants and existing manufacturers alike are looking to leverage biocidal claims. Yet while consumer demand is relatively consistent across different countries, worldwide regulatory frameworks are not. Various considerations need to be factored into any product development or marketing strategy, from permissible claims and terminology to active substance requirements. Harmonizing this across different countries or states can be a challenge.

Antibacterial laundry sanitizer has been purchased by 14% of adults on average across all six countries. The figure ranges from a high of 29% of adults in Spain to a low of 8% in the UK.





The US regulatory perspective

In the US, biocides for use on inanimate surfaces are regulated by the Environmental Protection Agency (EPA). However, there can be discrepancies between federal and state legislation.

For instance, biocides for controlling microorganisms which are infectious to humans are considered 'public health antimicrobials' when intended for use on inanimate objects. This covers use in any public setting, including homes.

Such products require registration both with the EPA and in any state where they are distributed. They are evaluated in terms of chemistry, toxicology, performance, and usage, according to guidelines established under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

The Canadian regulatory perspective

Disinfectant products for use on surfaces are regulated as drugs under Health Canada's Food and Drugs Act because they decrease the chance of transmitting disease. The Natural and Non-prescription Health Products Directorate (NNHPD) reviews ingredients, uses and claims of these products before they can be marketed.

The EU regulatory perspective

Antibacterial surface disinfectants are considered biocidal products in the EU. As such, they fall under EU Biocidal Products Regulation (BPR) 528/2012 concerning the market placement and use of biocidal active substances and products.

Approval criteria for biocidal active substances are harmonized and set out at the EU level. They must be assessed by the Evaluating Competent Authority of a Member State to determine efficacy and establish safety in relation to human health, animal health and the environment. If relevant criteria are satisfied, approval is granted by the European Commission for use in certain Product Types (PTs). Those for use in the disinfection of surfaces, materials, equipment and furniture which are not in direct contact with food and feeding stuffs are classified as PT2. The disinfection of equipment, consumption utensils and surfaces for food or feed for humans and animals is covered by PT4.

For biocidal products, BPR authorization is generally granted at national level. Despite ongoing efforts at harmonization and mutual recognition procedures, some Member States may have specific requirements for their own national market.

Changes in the UK

Following the UK's departure from the EU single market and customs union, there is some uncertainty over how regulatory requirements might evolve. There are also questions surrounding the approval timeframes for active substances. For the short to medium term, rules in Great Britain (i.e. England, Scotland, Wales and associated islands) will remain similar to those of the EU as the GB Biocidal Products Regulation (GB BPR) is a copy of the EU BPR. However, there is likely to be a gradual divergence over time and TSG is keeping a close watch on the situation.

What do consumers want?

Regulations focus on the efficacy and safety of products, and this largely corresponds with what consumers want from them. However, there are nuances which may offer opportunities for product differentiation without compromising regulatory compliance.

When we asked survey respondents which factors were important to them when purchasing products in response to COVID-19, there was a consistent 'top five' across all six countries (Figure 3):

1. The desire to protect self and loved ones (65%)
2. That the product does what it's supposed to (57%)
3. Good price/value (44%)
4. Functional claims (38%)
5. Scientific evidence of effectiveness (35%)

These factors point towards an overall consumer desire for 'products that work' while offering good value.

In addition, 79% of respondents agreed that availability of product-specific scientific data substantiating claims on manufacturer/retailer websites would give them confidence in the claims made. We found that 82% said the same about referencing a recognized scientific study on the product label/description (Figure 4).

All of these factors underline the benefits that can be realized from validation of claims and efficacy.

Going beyond baseline regulatory requirements to provide additional evidence of effectiveness may further enhance credibility and competitive differentiation. It's about conveying unique, proven benefits while satisfying regulatory demands. Combining proof of efficacy with additional factors can also be beneficial. For instance, we found that use of sustainable ingredients or materials was important to 27% of adults on average, and a quarter said the same about corporate social and environmental responsibility credentials.

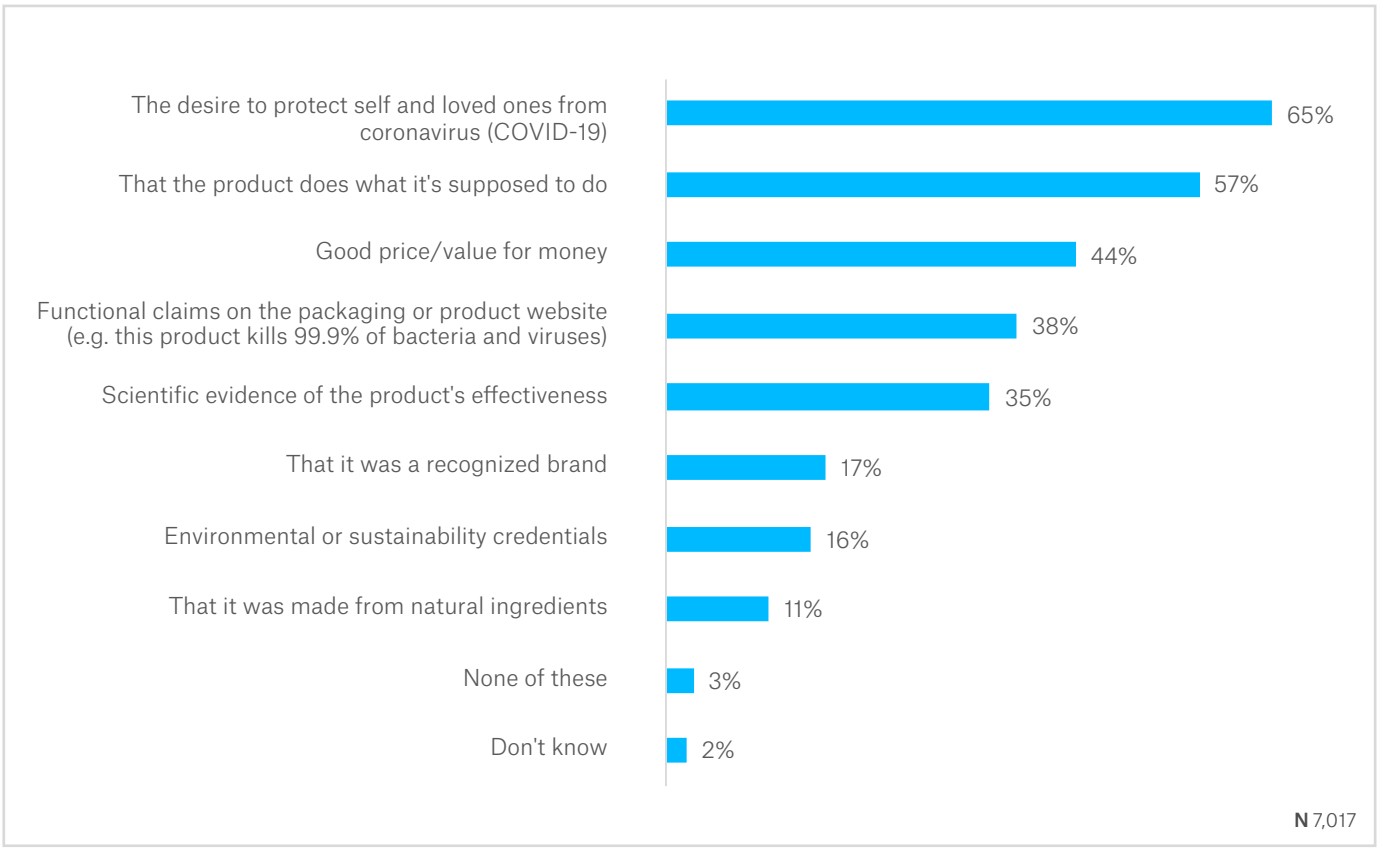


Figure 3: Findings related to the question "Thinking about any of the products mentioned previously that you have purchased for personal use because of coronavirus (COVID-19) (e.g. sanitizers, disinfectants, devices such as UV disinfection boxes, ozone sanitizing machines, foggers, etc.)... Which, if any, of the factors listed were important to you when deciding to purchase them? (Please select all that apply)"

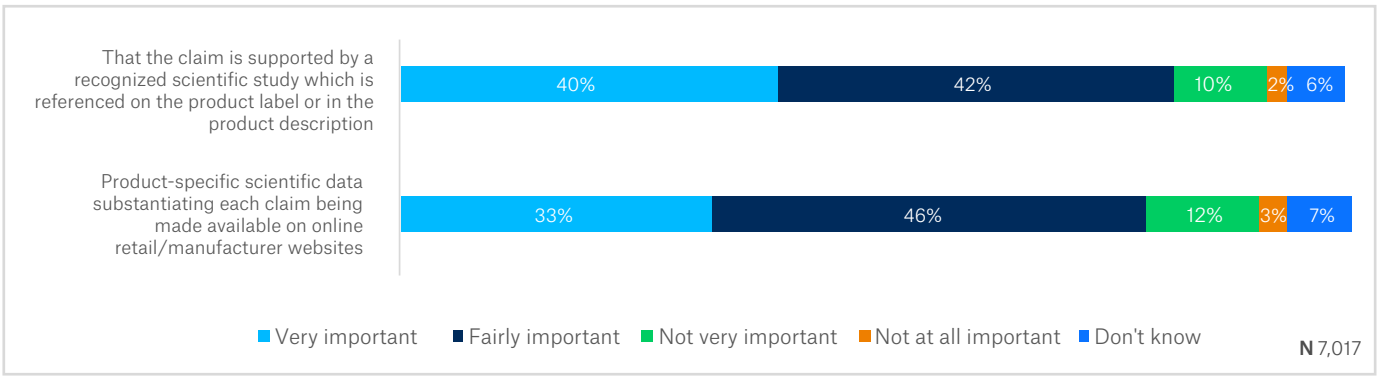


Figure 4: Findings related to the question "Still thinking about any of the products mentioned previously that you have purchased for personal use because of coronavirus (COVID-19)... How important, if at all, are these factors in giving you confidence in the product's effectiveness and claims made?"

Selling through online retailers

The rise of e-commerce via Amazon and other online retailers has opened new direct-to-consumer channels for manufacturers of household biocides as well as secondary sellers and distributors. This has raised concerns surrounding product efficacy and safety since inexperienced sellers may be unaware of regulatory requirements surrounding labeling, advertising, registration and reporting.

In the US, products subject to FIFRA requirements are increasingly being sold online. If they don't comply with the relevant regulations, both the seller and the online retailer can be held liable. Consequently, some online retailers are encouraging sellers to educate themselves on federal and state level responsibilities.

Amazon now requires US sellers of products that qualify as 'pesticides' or 'pesticide devices' under US regulations to complete and pass an online training program[2]. The course covers EPA regulations and definitions, various labeling requirements and common exemptions as well as guidance for e-commerce sales. Sellers that don't complete the training risk having their listing removed and being barred from creating new listings for similar products.

It remains to be seen whether more online retailers will follow suit, or if Amazon will extend this obligation to cover regulatory requirements in other markets. In the UK, Amazon sellers are currently expected to ensure any product claims are compliant with applicable regulations and are not misleading. Any specific product claims related to COVID-19 are prohibited in the EU and the UK alike. Amazon's guidance to UK sellers reflects this[3].

Equipment for disinfecting the home and personal items

Of the six countries we surveyed, respondents in the US and Spain are most likely to have purchased products such as UV disinfection devices or fogging machines in response to COVID-19 (Figure 5). These products are intended for areas that standard disinfection might miss or to disinfect materials or items that cannot be wetted. The percentage of people who have bought these products is far lower than that for traditional household biocidal products. However, it's worth noting that the figures are nationally representative, and therefore indicate that tens of millions of adults have purchased at least one piece of equipment to help disinfect their home or personal items.

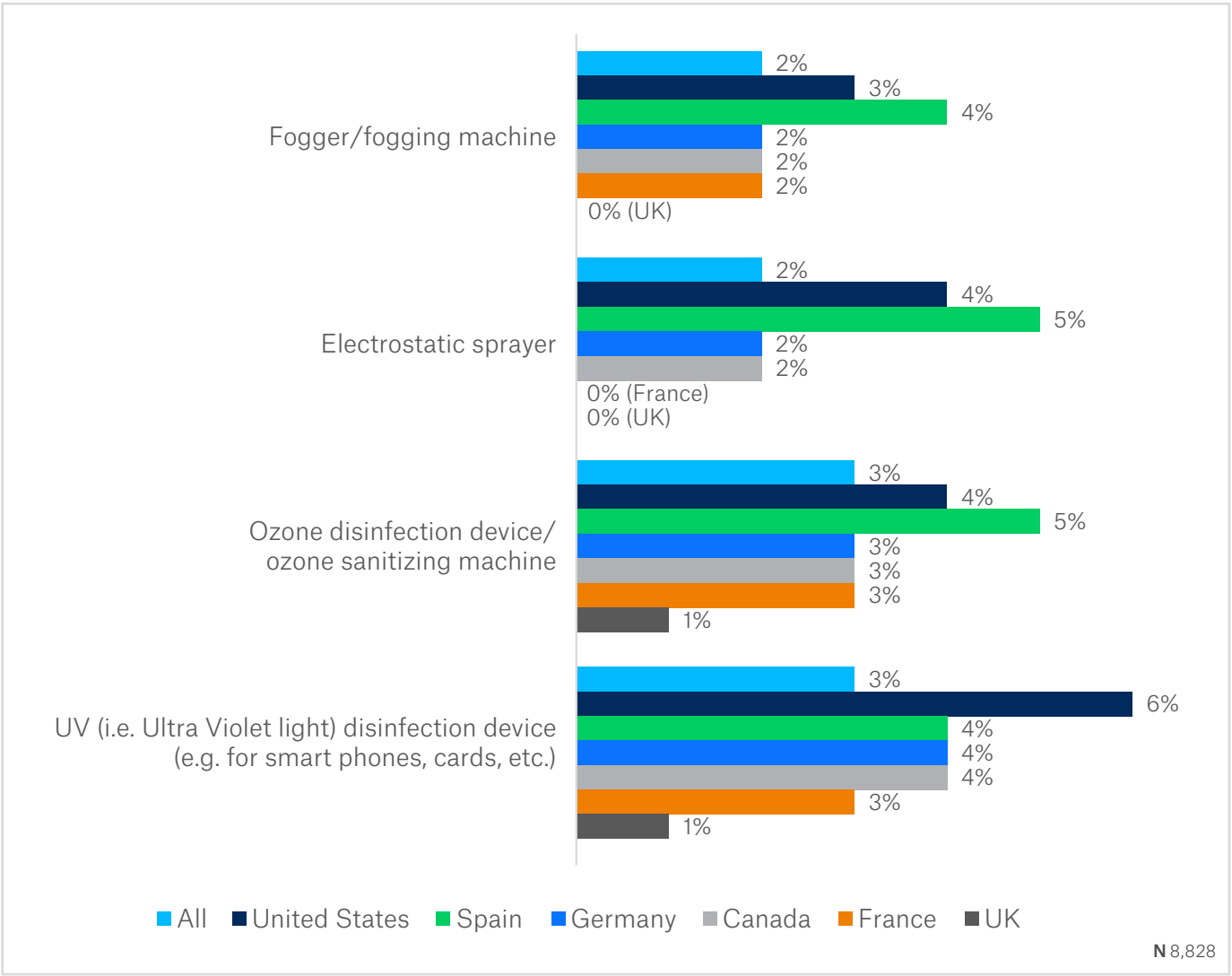


Figure 5: Percentage of consumers purchasing equipment for disinfecting the home and personal items in response to COVID-19

UV disinfection devices have been purchased by 6% of US adults and 4% have bought an ozone device. At present, products like these are largely unregulated at the federal or state level in the US. However, any claims related to their efficacy are subject to regulatory oversight.

In May 2020, the US EPA issued a Compliance Advisory[4] focused on devices that claim to kill SARS-CoV-2. With the agency receiving complaints concerning potentially false or misleading claims, it set out cautionary statements referring directly to products such as ozone generators and UV light devices. It advised that where these products have not been tested for efficacy or safety in their use against the novel coronavirus, such claims were unfounded.

Electrostatic products and fogging machines, used for the dispersal of biocides, have been bought by 4% and 3% of US adults respectively. While application equipment is not regulated per se, these products are intended for use with biocides which are heavily regulated.

Traditionally, electrostatic and fogging methods of disinfection have been deployed at an industrial level rather than in domestic settings. If the trend for consumers to purchase these items continues, it could have repercussions for the way biocide manufacturers sell and label products intended for use in them.

Under EU and GB regulations, ozone generated from oxygen is a biocidal active substance. Therefore, devices generating ozone are considered biocidal products and face similar requirements to 'standard' disinfectants.

Product claims

Claims related to the effectiveness and core properties of biocidal products are heavily regulated in all markets covered by our research. Statements on product labels and in product descriptions must clearly and accurately convey what the product can achieve without misleading consumers.

In the EU, Article 72 of the BPR looks specifically at advertising, legislating that *"Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy."*[5]

Nonetheless, according to our consumer research findings, there is room for improvement.

When we put the following statements to our study sample a significant majority were in agreement (Figure 6):

- It is difficult to find evidence on packaging or in product descriptions to determine whether claims are credible (67% agreed)
- Antimicrobial/antiviral claims on products are often unclear (72% agreed)
- I would like the data substantiating claims to be more accessible (81% agreed)

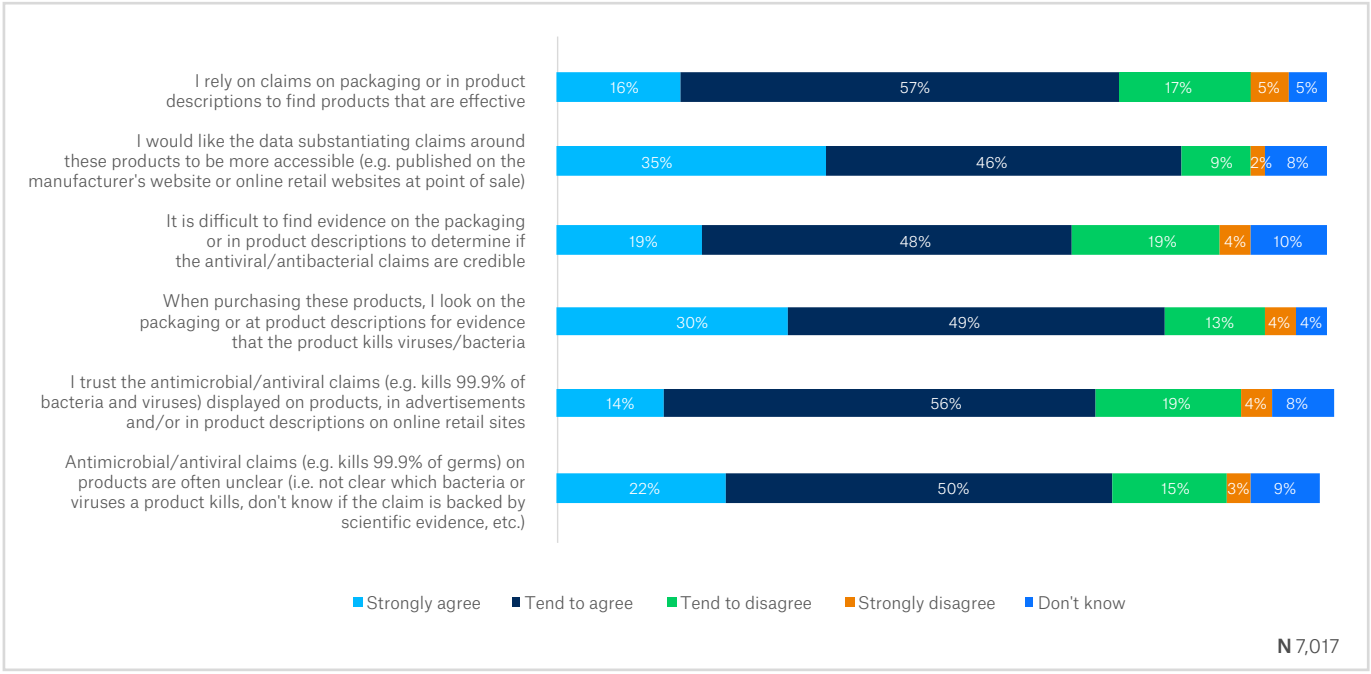


Figure 6: Findings related to the question "To what extent do you agree or disagree with the statements listed in relation to claims on these products?"

Product information has an important role to play in terms of both consumer decision making and regulatory compliance. We found that 73% of adults rely on labels or online descriptions to find products that are effective.

When we asked our survey respondents about product claims that matter to them, a clear majority (77%) said 'effectively killing germs or bacteria' was important (Figure 7). Knowing that products are manufactured to the highest safety standards was also important to more than half of consumers (54%). Again, this underlines the synergy between consumer expectations and regulatory requirements surrounding efficacy and safety.

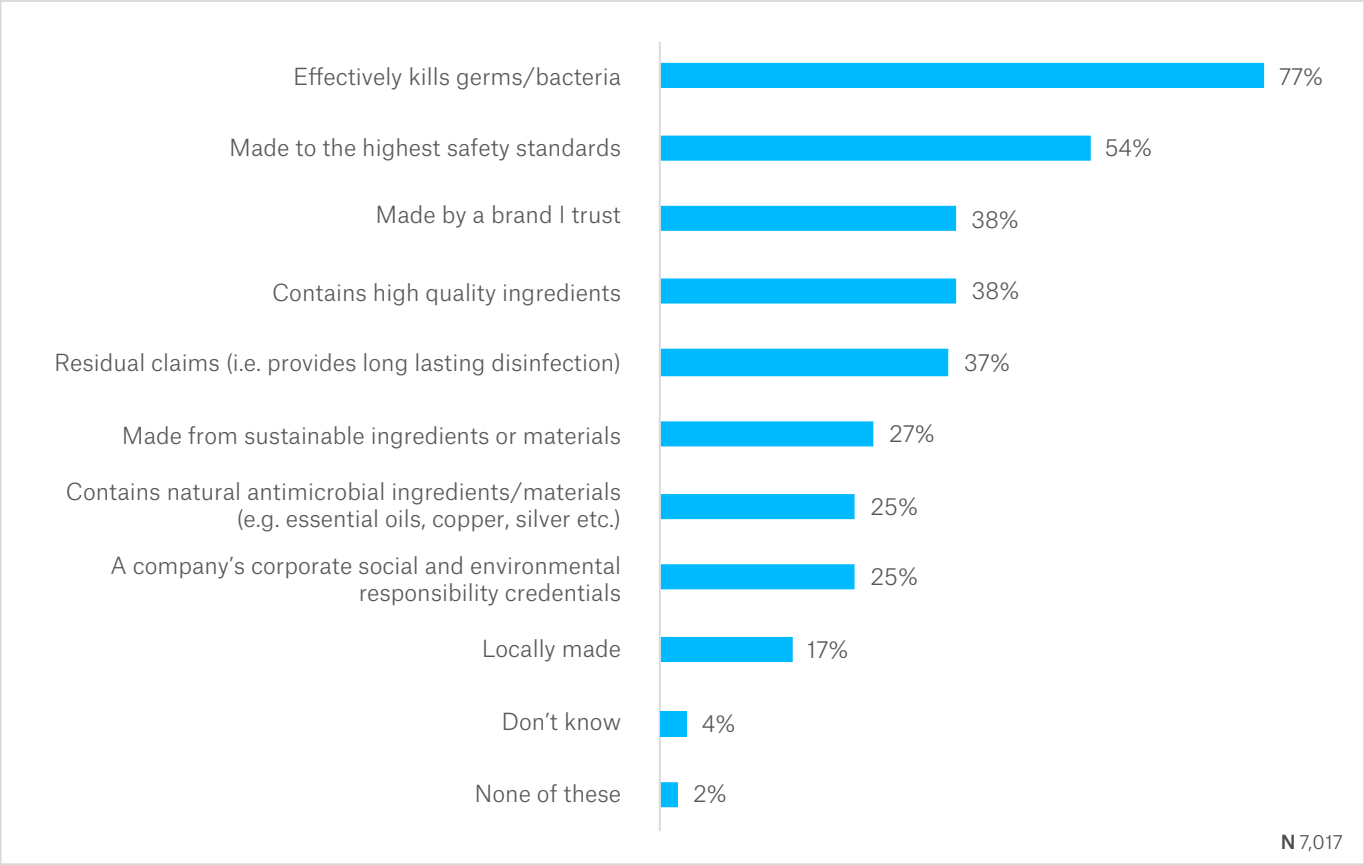


Figure 7: Findings related to the question "Which, if any, of the claims/features listed are important to you? (Please select all that apply)"

As mentioned earlier, 35% of adults say scientific evidence of effectiveness impacts their purchase decision (Figure 3). This figure may seem low in comparison to the 77% who want products which 'effectively kill germs or bacteria'. However, given the general lack of consumer availability of data to support claims, it is perhaps not surprising.

This disparity indicates that making scientific data more accessible – in terms of availability and ease of interpretation – could have a favorable impact on purchase decisions. Figure 4, illustrating factors which give consumers confidence in product claims, would appear to support this view. Moreover, generating substantive data for equipment such as electrostatic and fogging machines by testing them in conjunction with biocides could underpin the development of permissible efficacy claims.

Residual claims

In response to increased demand for products with long-lasting efficacy, the US EPA released a new draft guidance in October 2020. The goal is to expedite innovation in this category, getting new products to market as safely and quickly as possible. Yet while the registration process itself is faster, there are still rigorous requirements that must be satisfied to gain approval. Much of this relates to the development of data needed to substantiate the residual efficacy claims. This must be performed using specific efficacy test methodology and used in a compliant manner in product descriptions and on labels.

Our research findings underline the importance of residual efficacy to consumers. More than a third (37%) said that long-lasting disinfection was important to them (Figure 7). However, outside of the US it is not always possible to make claims of this nature. Canada is influenced by US protocol, but considers residual claims on a case-by-case basis. In the EU, when residual efficacy is claimed for dried products it must be demonstrated through efficacy tests. But residual claims are not common for disinfectants (unlike insecticides which are tested directly after application and at the end of the residual life of the product).

Validating efficacy

Robust scientific data is needed to substantiate efficacy claims, so products must be tested according to the relevant existing standards. Traditional biocidal products such as hard surface disinfectants are subject to well-defined performance standards and testing protocols. However, this is not always the case for equipment such as UV disinfection devices.

In the absence of prescriptive performance standards, the manufacturer must develop a testing protocol to support any claims made on the label or in online descriptions. The goal is to ensure testing is properly aligned with the intended efficacy claims, specific use or mode of action of the product. The protocol also needs to ensure the test method is repeatable in any test laboratory.

From the outset, it is important to be clear on the intended product claims and the associated data requirements. This enables study parameters to be defined, which ensures the appropriate quantitative data is produced. It's also necessary to consider how the data will be analysed and interpreted to ensure it is collected in the appropriate way. For companies without a scientist on staff, this is a good time to look for specialist guidance.

Whether the test involves an established protocol or a newly developed one, it's important to recognize permissible claims and associated efficacy levels in target markets.

In the EU, claims generally can't be made against a specific single species without claiming and demonstrating efficacy against the wider group of organisms. In addition, such specific claims cannot be made if they falsely imply the superiority of a product. Claims related to COVID-19 are therefore not possible for any application in the EU (unless a Member State decides otherwise) because no efficacy tests are carried out with SARS-CoV-2.

Nevertheless, testing can offer alternative ways to differentiate a product from the competition. In some scenarios optional testing on spores or field testing might be advisable, for instance to substantiate the claims for equipment such as fogging machines used in conjunction with biocides.

Final thoughts

Striking an effective balance between regulatory requirements and consumer expectations is no mean feat. However, it is possible to find synergy between the two.

Tests to validate claims from a regulatory perspective can be conducted and summarized in a way that resonates with consumers. The findings of scientific studies might be leveraged to generate unique evidence-based claims for competitive differentiation. Some data might be referenced on product labels and in online descriptions, but to further increase consumer trust more detailed information could be held on a separate webpage.

With a carefully planned approach, manufacturers can develop and convey product information that engages and influences consumers while satisfying regulatory needs across multiple markets, countries and states. When efforts to comply with regulation and achieve differentiation are aligned, it leads to better business efficiency, effectiveness and transparency. In a world reshaped by COVID-19, this is more important than ever.

How TSG can help

We offer a wide range of services and support in the US, Canada, EU, Switzerland, Norway and Great Britain. This includes, but is not limited to:

- Full US state and federal registration and renewal service, including obtaining company numbers and establishment numbers and coordination with the EPA, Canada's PMRA and the EU BPR. Support with FDA OTC monograph drug registration and listing.
- A comprehensive pan-European infrastructure to meet the challenges presented by differing requirements across Europe with offices in France, Germany, Spain and Great Britain offering focused, local registration support.
- Support for additional non-EU countries including Great Britain, Switzerland and Norway.
- Services include the development and review of antimicrobial/biocidal product claims and labeling, guidance on testing requirements, preparation and submission of applications for registration.

Notes

1. Biocides Overview, European Commission website (Public Health), https://ec.europa.eu/health/biocides/overview_en
2. Pesticides and Pesticide Devices, Amazon Seller Central (US), https://sellercentral.amazon.com/gp/help/external/202115120
3. Prohibited Product Claims, Amazon Seller Central (UK), https://sellercentral.amazon.co.uk/gp/help/external/help.html?itemID=6GFTJ2TEFCTKN6Q&language=en_GB&ref=efph_6GFTJ2TEFCTKN6Q_cont_201743940
4. EPA Issues Compliance Advisory Regarding Pesticide Devices Making Claims to Kill the Novel Coronavirus, *National Law Review*, June 9 2020, https://www.natlawreview.com/article/epa-issues-compliance-advisory-regarding-pesticide-devices-making-claims-to-kill
5. Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF

About TSG Consulting ¬

TSG Consulting provides companies with high quality regulatory and scientific consulting services.

We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments, and in industry.

This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance. TSG Consulting has offices in France, Germany, Spain, UK, USA and Canada. TSG is a Science Group (London listed) company.

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- R&D Consultancy: providing advisory, applied science and product development services cross sector helping clients derive maximum return on their R&D investments.
- Regulatory & Compliance: helping clients in highly regulated markets to launch, market and defend products internationally, navigating the frequently complex and fragmented regulatory ecosystems.
- Frontier Smart Technologies: designing and manufacturing chips and modules for the DAB/ DAB+ radio markets with 80% market share (excluding the automotive market).

With more than 400 employees worldwide, primarily scientists and engineers, and speaking more than 30 languages collectively, the Group has R&D centers in Cambridge and Epsom with more than ten additional offices in Europe, Asia and North America.

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