CHSA
Cleaning and Hygiene Suppliers Association

White Paper

The evolution and regulation of chemical disinfectants

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Executive summary

An understanding of disinfection and preservation has existed since the ancient world, from salting, drying or smoking foods in the Ice Age to Hippocrates recognising the benefit of heat sterilisation of water. While the use of chemical disinfectants has been less understood than the use of heat there is evidence Arab physicians used mercury as an antiseptic as far back as the 4th century.

The first standardised test methods for assessing the antibacterial properties of disinfectants emerged by the late 19th century. As well as proving if the chemicals were effective, they gave a way to remove fraudulent products, offering better protections.

Regulation formally came to the European biocides market in 1998 with the introduction of the Biocidal Products Directive. It was superseded in 2013 by the Biocidal Product Regulation, which has been copied into GB law post-Brexit. The BPR requires manufacturers to prove all product claims are accurate. They must also ensure a product is safe for use and present this information clearly on the label, so it is easy for the end user to understand. Additionally, a product must make appropriate claims for its intended purpose and area of use, substantiated by evidence from testing.

There are multiple test requirements a product must undergo, based on the intended market(s). These requirements ensure every claim made about a disinfectant is supported by robust laboratory testing. This testing must use consistent and repeatable methods, that are comparable across any laboratory. Within each of these product types, there are multiple uses such as spray and wipe application, mopping, or fogging. Each application requires its own methods to prove the products suitability for disinfection in its specific area of use.

The guidance, regulations and test methods are continually evolving to keep pace with new technology. Today there are gaps. For example, no harmonised test methods exist for assessing products that claim to disinfect the air or that use ozone technology. There is also no test method that will verify residual activity beyond 24 hours. It means claims of this type cannot yet be verified within the regulatory framework.

Regulations are intended to ensure a cleaning product is safe for the user and the environment when used correctly. The aim of enforcing regulatory requirements is to ensure products on the market can be trusted and that the companies selling them maintain the highest standards of integrity.

Product innovation means testing and regulatory requirements in the biocide market are becoming more complex, and the costs to enter markets are rising. This is expected to lead to a rise in fraudulent products, bypassing or ignoring regulations. Many are making claims about safety and efficacy without the proper technical support from correct testing to capitalise on the public's heightened awareness of the risks posted by micro-organisms post pandemic. They are also using eco-friendly language to appeal to environmentally conscious consumers.

Buyers need to beware.

The evolution and regulation of chemical disinfectants

10,000 years of learning have led us here

An understanding of disinfection and preservation has existed since the ancient world. Evidence of salting, drying or smoking foods can be found in Ice Age sites of early humans, and references to heat sterilisation appear in Middle Eastern literature, including the Bible:

"Gold, silver, bronze, iron, tin, lead and anything else that can withstand fire must be put through the fire, and then it will be clean" - Numbers 31:21-24.

Persians knew that water stored in earthenware would spoil rapidly, but in vessels made of copper or silver, it would "remain sweet" for longer. In the 4th or 5th century, Hippocrates recognised the benefit of the heat sterilisation of water:

"Such waters are naturally the best. But they need to be boiled and purified from foulness if they are not to have a bad smell, and give sore throat, coughs and hoarseness to those who drink them." - De Aere Aquis et Locis.

In 1856, Pasteur proved that the spoiling of milk was caused by micro-organisms. He later used this discovery to create the process of pasteurisation, which is widely used in the industry today.

The use of chemical disinfectants has been less understood than the use of heat, however there is evidence that Arab physicians used mercury as an antiseptic dating as far back as the 4th century.

In the 1770's, chlorine chemicals were stabilised for the first time as a bleaching agent, and later as a disinfectant, introducing an active still used today.

By 1881, Robert Koch had assessed over 70 compounds for their antibacterial properties, effectively creating the first standardised test method for disinfectants. His work was later improved upon by Geppert in 1889, who introduced a neutraliser to the test to ensure a definitive end point to an evaluation. These tests aimed to prove a product was effective at the destruction of harmful organisms. It meant that we went from the discovery of germ theory in the 1860s to a method of substantiation for disinfectants within 20 years. The tests aimed to prove chemicals were effective but hand-in-hand they gave a way to remove fraudulent products, offering better protections in hospitals at a time where Sir James Young Simpson described the outlook of surgery as: 'A man laid on the operating table in one of our surgical hospitals is exposed to more chance of death than was the English soldier on the field of Waterloo.'

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The principles of the original tests in the 1880's laid the groundwork for all the test methods that arose over the next century. By the 1970's, multiple methods had been developed worldwide to demonstrate, quantifiably or qualitatively, the effect of chemicals used as disinfectants.

This introduced a new problem for the growing chemical industry: varying international requirements for disinfectants. This made it difficult to compare products across different markets. As the market globalised, products had to be tested according to each country's methods to stay compliant, or else they could not be sold there. This was costly and time-consuming. Furthermore, a product suitable for one market might not pass another's tests without being grossly over strength, posing additional risks to users and the environment.

This lack of harmonisation hindered the development of new methods and slowed the adoption of the latest scientific practices. So, in 1989 the European Committee for Standardization set up Technical Committee 216 (TC/216) – Chemical Disinfectants and Antiseptics. This group was tasked with the development of harmonised methods to standardize the terminology, requirements, and test methods for chemical disinfectants.

Over the last 35 years this technical committee, along with the hundreds of experts in its working groups, have developed, maintained and regularly updated over 70 methods across multiple areas of use. They have also provided technical guidance documents used by governments and companies alike to ensure products are suitably tested and proven to meet their claimed protections.

Current biocide regulatory landscape

For much of its history, the biocides has been an unregulated market. This changed in 1998 with the introduction of the Biocidal Products Directive (BPD), also known as European Union Directive 98/8/EC. This legislation established the definition of a biocide that is still in use today:

"Active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means" – Article 2(1)(a)

This directive also broke down disinfectants into 23 key Product Types (PTs), which belong to four main groups: disinfectants and general biocidal products, preservatives, pest controls, and other biocidal products.

Thus began the first steps in regulating the market, defining product requirements, and establishing the registration process. These measures aimed to ensure that a product was as safe as possible for users the environment, in which it will ultimately be disposed.

In 2013, this directive was superseded by the Biocidal Product Regulation (EU) 528/2012. This regulation aimed to improve the biocide market's efficiency, whilst maintaining product safety. Key changes included classifying treated articles, such as materials containing silver, enabling data sharing between companies and competent authorities, and imposing stricter data requirements for products. These measures sought to reduce the requirement for animal testing through data sharing and ensure that all claims were backed by suitable testing.

The BPR requires manufacturers to prove all product claims are accurate, including its lifespan, its effectiveness in use, and its contents. They must also ensure a product is safe for use and present this information clearly on the label, so it is easy for the end user to understand. Additionally, a product must make appropriate claims for its intended purpose and area of use, substantiated by evidence from testing.

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In the UK, the Health and Safety Executive (HSE) is the Competent Authority for Biocides. Each member state has its own Competent Authority responsible for the assessment of a product and its BPR dossier, while the European Chemicals Agency (ECHA) is responsible for driving legislation forward. These entities can be consulted for advice on complying with this regulation. The existing EU Biocidal Products Regulation (EU BPR) has been copied into GB law and amended to enable it to operate effectively in GB. This means that most aspects of EU BPR will continue in the same way under the new GB Biocidal Products Regulation (GB BPR) that came into force on 31 December 2020.

With the introduction of the BPR came Article 95, which was introduced in 2015. The underlying aim of the Article 95 list is to establish a level playing field in the market for active substances. Since September 2015, a biocidal product cannot be sold on the EU market unless either the substance supplier or the product supplier is included in the Article 95 list for the relevant product type (PT). ECHA is responsible for creating and routinely updating this list based on compliant applications from suppliers.

Following Brexit there was one major change for GB based chemical suppliers and this was that they had to resubmit Applications for Active Substance approval and Product Authorisation. These had to be resubmitted to the UK Health & Safety Executive (HSE) from January 2021 and that companies must be established in the UK to be listed on UK Article 95. The reason for this was the HSE could no longer access data and information in the EU databases and IT systems.

Efficacy test requirements and guidance

ECHA is responsible for creating guidance for BPR legislation in the EU and the HSE is responsible in GB. This includes the information requirements and procedures for conducting the mandatory assessments. The guidance is split into five parts. Volume 2 specifically addresses efficacy claims, with Part A detailing the information requirements and Parts B and C covering the assessment and evaluation processes.

Parts B and C are the more complex sections of the documents, outlining the multiple test requirements the product must undergo, based on the intended market(s). These requirements ensure that every claim made about the product is supported by robust laboratory testing. This testing must use consistent and repeatable methods, that are comparable across any laboratory. Most disinfectants fall under Product Types (PT) 1 – 5:

1. Human hygiene biocidal products
2. Disinfectants and algaecides not intended for direct application to humans or animals
3. Veterinary hygiene biocidal products
4. Food and feed area disinfectants
5. Drinking water disinfectants

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Within each of these product types, there are multiple uses such as spray and wipe application, mopping, or fogging. Each application requires its own methods to prove the products suitability for disinfection in its specific area of use.

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The areas of use are categorised as either Medical, Veterinary, or Food, Feed, Domestic, Janitorial and Industrial. Each of these areas of use has its own working group within the CEN/216 technical committee, who develop and maintain methods to cover most use cases.

To be classified as a disinfectant, a product must claim effectiveness against a type of organism. The minimum requirement for a disinfectant is a claim against bacteria and yeast. Guidance also details multiple optional claims including efficacy against fungi, bacterial spores, mycobacteria, viruses, bacteriophages and algae. The guidance provided by ECHA is based on the work and input from the CEN groups. To further this, TC/216 has released EN14885, which breaks down the methods used to support claims. This document provides clear templates of the required methods for each area of use by application.

Regulation and test methods – from principle to practice

When discussing the required testing for a product, it is easier to work with an example. For this purpose, let's consider a new company entering the disinfectant market with a liquid product based on Quaternary Ammonium Compounds (QUATs), intended for use in facilities management. The company wants to market it as a suitable for spray and wipe applications, mopping floors, and use with their fogging device for whole room disinfection in hotels. They intend to claim it is effective against all germs and enveloped viruses. Regulations state that the active substance must come from a suitable article 95 supplier registered with ECHA. This ensures that the raw material meets necessary standards and that key information about the raw material is known to the market. Using the ECHA guidance Volume 2 – parts B and C, the product is defined as Product Type (PT) 2: a disinfectant not intended for direct application to humans or animals. According to CEN, the product falls under janitorial use.

With this designation, the company can now seek to prove its claims using the tests detailed in EN14885, which in this case would be:

- EN 1276 – Bacterial suspension test
- EN 1650 – Yeast suspension test
- EN 13697 – Bacteria and Yeast surface test
- EN 14476 – Virucidal suspension test – Enveloped virus claim – Janitorial use conditions
- EN 17272 – Airborne disinfection – Bacteria, Yeast and viruses

In all cases, testing should be conducted using the most up-to-date version of the method. It should be repeated in the future if significant changes occur to any method. The aim of any test should be to replicate its use instruction as closely as possible in a laboratory setting. This means that the test conditions should include the correct dilutions of product, interfering substances at expected levels, and a reasonable contact time. For example, a spray and wipe product should have a contact time of one minute, rather than 60 minutes, as the latter would be an unreasonable expectation of use.

Each test method has specific criteria to demonstrate an adequate level of disinfection for the intended use. If a product fails to reach the appropriate level of disinfection, it cannot make the claim, regardless of how close it may be to the necessary standard. A product should be tested against all required organisms in a standard, achieve the log reduction specified by the standard, and be tested in the presence of an interfering substance appropriate to the area of use. All of this information is included in the EN14885 document, which should be used by both manufacturers and buyers to ensure their products meet every requirement.

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What isn't covered by current guidance

Guidance and regulations are continually evolving to keep pace with new technology and the claims that companies wish to make. As a result, there are multiple gaps and exemptions in regulatory guidelines.

UV disinfection: Currently UV disinfection is not covered under the BPR as it does not involve chemical or biological means. Until 2022 no harmonised test methods were available. However, with the publication of BS 8628:2022, there is now a standard that defines the level of disinfection that products must achieve to be deemed effective.

Disinfection of the air: In the aftermath of the pandemic, air quality has become a much higher concern in many industries, aiming to limit the impact of future illnesses transmitted by coughing or sneezing. Currently, there is no harmonised method for assessing the disinfection or purification of air in confined spaces.

Ozone technology: All current test methods are designed for the testing of aqueous products. Gaseous products like ozone and other charged ion technology, cannot be effectively tested in the currently published test methods.

Long term residual activity: Although PAS 2424 is a draft method and not fully published or supported, it is used to make a 24 hour claim of residual activity. Currently, there is no development to allow for claims beyond a 24-hour period.

Algacidal claims: Whilst there are some methods available, no specific guidance is currently provided by either CEN or ECHA. Development to close this gap is underway.

Drinking or leisure water treatment: Whilst test methods are based around aqueous products, there is no available method to provide specific guidance for the treatment of water under PT 5. This leads to multiple bespoke modifications which are not readily repeatable between manufacturers.

In situ generated biocides: An in situ generated biocide does not need to be registered on the article 95 list, however, its precursor chemicals do require registration on the list. In situ generated biocides are biocidal active substances that are created at the point of use, rather than being packaged and sold as a finished product, common examples are Ozone, active chlorine and some hydrogen peroxide products.

New active substances/technologies: Products based on completely new technology or raw materials not previously available on the market, cannot be sold without first being registered as an active substance. Specific data must be submitted to ECHA or the HSE. This would include any chemical not previously available to the market or actives that have been sufficiently modified as to no longer be classed at the active it began as.

What does the future hold

The future of biocide testing requirements for products will become more specialised with the closure of data gaps in multiple areas of use, and increased testing to support claims in currently uncovered areas. As of 2024, multiple methods are in development for virucidal, algacidal and sporicidal claims, as well as methods specialised in demonstrating the effectiveness of products like wipes, where only one method is currently available to the public. However, with the introduction of new methods, it will become much clearer what tests a product will require, reducing the need for interpretation when choosing the correct conditions for efficacy testing.

The regulatory future of biocides is one of increased requirements for many products as they progress through the BPR process. Additionally, there may be a return to some level of disparity between the EU and UK with the introduction of the UK BPR and a UK Article 95 list. This post-Brexit move suggests a shift away from EU documents in the future. While the exact changes are currently unknown, all manufacturers of products and raw materials will need to stay informed.

As for the future of the biocide market, testing and regulatory requirements are becoming more complex, and the costs to enter markets are rising. Competent Authorities are under increased pressure as multiple actives undergo their BPR dossier process, with several authorities facing resource issues for market monitoring. This situation is expected to lead to a rise in fraudulent products. Initially driven by the COVID outbreak response, which temporarily allowed unregulated products to enter the market, the rise of drop shipping and the anonymity of e-commerce sales have further exacerbated this issue. Many products are entering the market without the proper listing with ECHA and, in many cases, are making claims about safety and efficacy without the proper technical support from correct testing.

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Biocide fraud: what to look out for

It is important to remember that these regulations are intended to ensure a cleaning product is safe for both the user and the environment when used correctly. The aim of ECHA and all competent authorities involved in enforcing regulatory requirements is to ensure that products on the market can be trusted and that the companies selling them maintain the highest standards of integrity.

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Disinfectants and cleaning products are inherently dangerous and represent the most common daily exposure to hazardous chemicals in many households and businesses. A chemical whose sole purpose is the control or destruction of microorganisms could if mishandled or misused pose a risk, some more than others. No chemical is entirely without risk or safety concern if used incorrectly. Without the correct information on its use or the best practice for handling a disinfectant it poses an unnecessary risk. This may not be as serious as injury but even products deemed generally safe can be irritants or corrosive with enough exposure or incorrect use. By ensuring that the data on exposure, environmental impact, stability and efficacy have been provided for the products sold in the market, their use can be minimised, used as intended, no more than needed, and for a purpose that they are effective at controlling.

There is a rise in the number of products that bypass or ignore European regulations, taking advantage of the public's heightened awareness of the risks posed micro-organism post pandemic. These products use eco-friendly language to appeal to environmentally conscious consumers, making unsubstantiated claims to profit from this trend. When a product makes claims of safety or eco friendliness that seems too good to be true it may well be. A product being ecofriendly does not necessarily mean it is safe and remember that when you see words like green, all natural, organic, ecofriendly, and environmentally friendly on a cleaning product label, they have no legal meaning.

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End users and manufacturers need to be aware of the requirements a product must meet to make informed choices. A test to show that a product can kill 99.99% of bacteria is not just a label claim but an assurance to the end user that the product will not leave behind harmful organisms that could harm them, their families or their customers.

Over thousands of years, disease has been a great leveller of society in ways we do not see today, due in part to advancements in understanding how illnesses spread and how chemicals can be employed to reduce that risk. Now, in a collective effort, the industry is moving towards not only providing protection against illness but also mitigating the environmental impact these products produce.

Companies that operate outside regulation face consequences ranging from market removal to financial and legal repercussions.

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