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DISINFECTANTS, REGULATION AND REQUIREMENTS - GLOBAL OVERVIEW

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ABSTRACT: Surface disinfectant is the multi-billion-dollar global industry with continuous growth opportunities linked to advancements in technology and innovations. However, innovations and new advancements do not always reach consumers due to the lack of clarity related to the approval process of such innovations and stringent regulations by national health authorities. These regulations can pose challenges for innovators, manufacturers, Importers & exporters to obtain Market Authorizations. This article provides an overview of the disinfectant regulations globally and understands the need for harmonization.

INTRODUCTION: Disinfectants (Also known as Biocides in some of the geographical regions) are the active substances or preparations that contain one or more active substances, that are presented to the user in their final form, and whose function is to destroy, stop the growth, make harmless, avoid or control by any mean the action of a pathogenic organism by a biological or chemical process ¹. Disinfectants do not necessarily kill all organisms but reduce them to a level, which does not harm health or the quality of perishable goods. Disinfectants are applied to inanimate objects and materials such as instruments and surfaces to control and prevent infection. They may also be used to disinfect skin and other tissues before surgery. The most common methods of disinfection following worldwide by the application of chemical compounds like alcohols, aldehydes, anilides,

Biguanides, bis-phenols, diamidines, halogen-releasing agents, halophenols, peracetic acid, heavy metal derivatives, peroxygens, phenols and cresols, quaternary ammonium compounds (QACs), chlorine-releasing agents and ozone ^{2,3}.

Each bacterial strain reacts differently to each chemical compound, either by its phenotypic characteristics (*e.g.*, properties of the cell wall) or due to resistance mechanisms (coded by its genotype or induced). Thus, it is fundamental that when selecting one or more biocides, an evaluation of the efficacy on the eradication of dominant microorganisms present on that system is performed. Only after having information about the nature of the microbial population to treat it is possible to determine the relationship between the minimum inhibitory concentration and the contact period of a biocide to a given contaminant ⁴. Within biocide mechanisms of action, four major categories can be found:

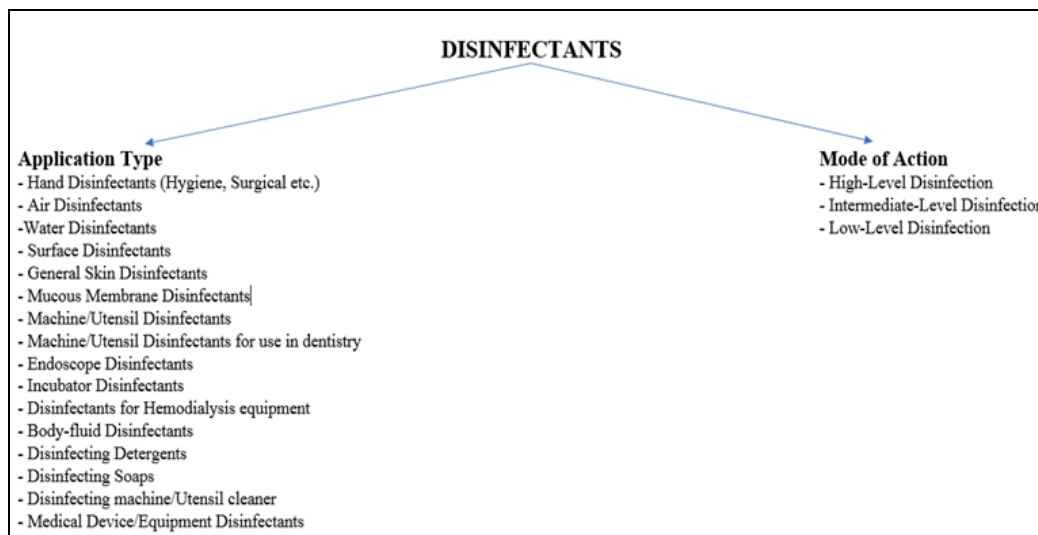
1. Oxidants,
2. Electrophilic agents,
3. Cationic membrane biocides,
4. Weak acids.

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Oxidants act *via* radical-mediated reaction oxidizing organic material; electrophilic agents react covalently with cellular nucleophiles to inactivate enzymes; cationic membrane active biocides destabilize membranes leading to rapid

cell lysis; and finally the weak acids interfere with the ability of the cell membrane to maintain a proper pH balance, resulting in acidification of the cell interior and widespread disruption of metabolism⁵.

Type of Disinfectants:



Mechanism of Action: Disinfectants act on microorganisms in two ways:

1. Growth inhibition (bacteriostasis, fungistatic);
2. Lethal action (bactericidal, fungicidal, or virucidal effects).

Only the lethal effects are of interest in disinfection and, as the objects of treatment have no inherent means of defense, lethality is the desired objective⁶.

A classical approach which is used to determine the mechanism of action of a biocide establishes a correlation between the minimum inhibitory concentration and the resulting biochemical and physiological changes in the organism⁷. An antimicrobial effect can be defined as an interaction between an active substance and specific targets in the microbial cell. In the target approach, the active ingredients contact with a variety of cellular structures (cell wall, cytoplasmic membrane, membrane enzymes, cytoplasm, and genetic material). Different strains revealed that Gram-negative bacteria, which have the supplementary protection of the cell wall, are more resistant to the bactericidal effects than gram-positive bacteria^{8, 9, 10}. The biocides pass through the cell wall by pores (porin). This penetration, according to Paulus¹¹, is

dependent on the size, charge, and lipophilic properties of molecules. If a substance is soluble in water and its molecular weight is around 600Da, there is a great probability of passing through the channel formed by the porin. It is also possible that the biocide penetrates the cell wall after causing its destabilization and disintegration. Finally, the biocide reaches the cytoplasmic membrane as the primary site of action. Depending on the action spectrum, these substances could be designated as biostatics (if they only inhibit the microorganism growth or multiplication) or as biocides (if they can kill the microorganisms).

The process of transporting the biocide to the cell surface, adsorption, diffusion, penetration, and interaction with the target cell component is not instantaneous, and the duration of this process can be different accordingly to the biocide. The differences depend on the action mode, as well as the chemical composition and physicochemical properties of the biocidal agent. Biocidal compounds come from a variety of chemical classes. **Fig. 1** shows the antimicrobial mode of action of biocide on diverse types of microorganisms. Generally recognized disinfectant substances, mechanism of action and applications^{12, 13}.

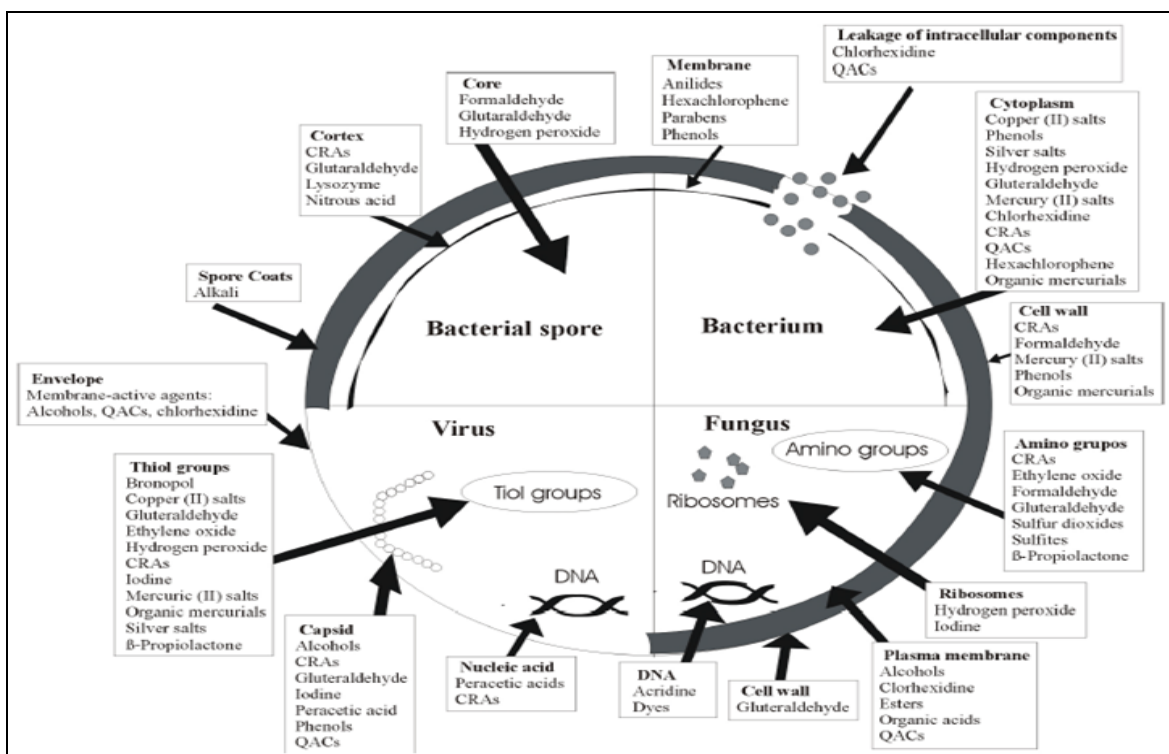


FIG. 1: ANTIMICROBIAL MODE OF ACTION OF BIOCIDES. CRAS – Chlorine Removal Agents; QACS – Quaternary ammonium Compounds

TABLE 1: GENERALLY RECOGNIZED DISINFECTANT SUBSTANCES, MECHANISM OF ACTION AND APPLICATIONS^{12,13}

Substance Group	Substance	Mechanism of action	Application
Alcohols	Ethanol, Isopropanol	Protein denaturation in cytoplasm & membrane	Antisepsis, disinfection, preservation
Aldehydes	Glutaraldehyde, Formaldehyde, 0-phthalaldehyde	Alkylation of amino groups in proteins & nucleic acids	disinfection, sterilization, preservation
Anilides	Triclocarban	Inhibits fatty acid synthesis, membrane damage at high concentrations	Antisepsis, deodorant
Biguanides	Chlorhexidine, Alexidine, Polymeric biguanides	Bonding to phosphate groups and phospholipids fatty acid chains in cell membranes	Antisepsis, anti-dental plaque substance disinfection, preservation
Bisphenols	Triclosan, Hexachlorophene	Inhibits enzyme in fatty acid synthesis, at high concentrations non-specific. Membrane damage inhibits electron transport chain in membrane	Antisepsis, anti-dental plaque substance deodorant, preservation
Diamidines	Propamidine, Dibromopropamidine	Membrane damage, amino-acid leakage	Antisepsis, preservation
Halogen-releasing compounds	Chlorine compounds, iodine compounds	Oxidation of thiol groups, Halogenation of aromatic amino acids in proteins	Antisepsis, disinfection, cleaning
Halophenols	Chloroxylenol (PCMX)	Probably membrane damage	Antisepsis, disinfection, preservation
Heavy Metals	Silver compounds, Mercury compounds, Copper compounds, Zinc compounds	Interaction with protein thiol groups	Antisepsis, disinfection, preservation
Peroxides	Hydrogen Peroxide, Ozone, Peracetic acid	Oxidation of thiol groups and double bonds	Disinfection, sterilization, anti-sepsis
Phenols & Cresols	Phenol, Cresol	Protein denaturation in cytoplasm and membrane	Disinfection, preservation
Quaternary ammonium compounds	Cetrimonium chloride, Benzalkonium chloride, Cetylpyridinium chloride	Bonding to phosphate groups and phospholipid fatty acid chains in cell membranes	Antisepsis, disinfection, preservation, cleaning, deodorant
Gas-forming Substances	Ethylene oxide, formaldehyde	Alkylation of amino groups in proteins & nucleic acids	Sterilization, disinfection

Market Size: The global surface disinfectant market is predominantly driven by the increasing awareness generally about hygiene and cleanliness among individuals. The rising education level and rising disposable incomes in emerging economies resulting in increasing use of disinfectants to prevent germs from breeding are also acting in favor of the market. The global surface disinfectant market to grow at a Compound Annual Growth Rate (CAGR) of 11.70% during the period 2017-2021. Increasing healthcare expenses, increasing number of hospital-acquired infections, and increasing surgical operations are expected to drive market growth in the coming years. One trend in the market is increasing innovative products. The introduction of innovative products or technology will drive the market in the forecast period. Manufacturers of surface disinfectants are adopting new technologies to enhance the efficiency of the products, differentiating them from the existing ones.

According to OECD (Economic Survey of the United States) data, the expenditure on healthcare by the US in 2016 accounted for 17.2% of the GDP, and it is estimated to account for around 18.5% of GDP by 2021.¹⁴ Healthcare expenditure is an integral part of national as well as domestic budget. The rapid increase in healthcare expenditure is anticipated to foster the product demand. Surface disinfectant is used to disinfect and sanitize surfaces such as floors, furniture, washrooms, tiles, walls, instruments, and clothes.

According to the World Bank estimates, global healthcare expenditure has witnessed remarkable growth from USD 3,786 billion in 2003 to USD 7,427 billion in 2013, growing at a CAGR of 7% over the forecast period. In the same period, public healthcare spending increased at a CAGR of 7.28%, from USD 2,198 billion in 2003 to USD 4,440 billion in 2013. This high growth rate along with huge size of healthcare spending, is expected to drive surface disinfectant market growth.

Rapidly increasing geriatric population and consequent rise in chronic diseases have increased health issues. Increasing incidents of infectious and human-transmitted diseases, especially within healthcare workers, have put forward the need for surface disinfection in hospitals. Government

initiatives to increase awareness regarding need for cleanliness and disinfection are expected to foster market growth. Rising awareness regarding home cleanliness and need for disinfection is also expected to fuel the product demand. Rising disposable income coupled with increasing focus on child health has positively affected the home disinfectants demand. Recent infectious disease outbreaks such as Ebola, influenza, and chikungunya are expected to fuel the surface disinfectant demand over the forecast period.

Based on product, the market is segmented as quaternary ammonium compounds, peracetic acid, hypochlorite, chlorhexidine gluconate, phenolic compounds, aldehydes, iodine compounds, chlorine dioxide, hydrogen peroxide, and alcohols. Hypochlorite held maximum market share in 2014 and is expected to lead the market over the forecast period. Hypochlorite is primarily used for bleaching, disinfection, and water treatment. Quaternary ammonium compounds are expected to witness the fastest growth on account of their more effective and biodegradable nature.

Based on formulation, products are classified as liquids, sprays, and wipes. Liquid disinfectants account for the largest share in the global market and are expected to be the fastest growing segment over the forecast period. North America holds maximum share in the global surface disinfectant demand and is expected to retain its position over the forecast period. High standards of living have driven home cleanliness and other hygienic habits in consumers. Government initiatives and enforcement regarding public health and hygiene have also driven market growth.

Asia Pacific (APAC) is expected to be the fastest growing region over the forecast period. APAC is driven by increasing population along with increasing government expenditure on public health and cleanliness. Increasing disposable income in addition to rising consumer awareness regarding the need for cleanliness and hygiene is expected to foster the product demand over the next seven years. Increasing healthcare spending in Middle East countries, including Kuwait, Saudi Arabia, and the UAE is expected to create new opportunities for the key players in the region. Backwardness in the healthcare sector in Africa

region is also expected to offer huge growth potential over the forecast period ¹⁵.

United States Regulation: In the United States, liquid chemical germicides (disinfectants) are regulated by the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). In health-care settings, EPA regulates disinfectants that are used on environmental surfaces (house-keeping and clinical contact surfaces), and FDA regulates liquid chemical sterilants / high-level disinfectants (*e.g.*, glutaraldehyde, hydrogen peroxide, and peracetic acid) used on critical and semicritical patient-care devices. Disinfectants intended for use on clinical contact surfaces (*e.g.*, light handles, radiographic-ray heads, or drawer knobs) or housekeeping surfaces (*e.g.*, floors, walls, or sinks) are regulated in interstate commerce by the Antimicrobials Division, Office of Pesticide Programs, EPA, under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), compliance to 40 CFR 152. Under FIFRA, any substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, including microorganisms but excluding those in or on living man or animals, must be registered before sale or distribution.

EPA requires manufacturers to test formulations by using accepted methods for microbicidal activity, stability, and toxicity to animals and humans. Manufacturers submit these data to EPA with proposed labeling. If EPA concludes a product may be used without causing unreasonable adverse effects, the product and its labeling are given an EPA registration number, and the manufacturer may then sell and distribute the product in the United States. FIFRA requires users of products to follow the labeling directions on each product explicitly ¹⁶.

All products must be registered if:

A) The person who distributes or sells claims, states or implies that the substance is intended for a pesticidal purpose (*i.e.*, used to prevent, destroy, repel or mitigate harmful microorganisms).

B) The substance consists of one or more active ingredients and does not have a significant commercially viable use other than its use as a pesticide.

C) Labeling: EPA registered pesticides must be labeled by 40 CFR 156. Please refer to the actual regulation to determine exactly what information is required on the label ¹⁷.

Classification:

i) High-Level Disinfection: This procedure kills vegetative microorganisms and inactivates viruses, but not necessarily high numbers of bacterial spores. Such disinfectants are capable of sterilization when the contact time is relatively long (*e.g.*, 6 to 10 h). As high-level disinfectants, they are used for relatively short periods (*e.g.*, 10 to 30 min). These chemical germicides are potent sporicides and, in the United States, are classified by the FDA as sterilant/disinfectants. They are formulated for use on medical devices, but not on environmental surfaces such as laboratory benches or floors.

ii) Intermediate-Level Disinfection: This procedure kills vegetative microorganisms, including *Mycobacterium tuberculosis*, all fungi, and inactivates most viruses. Chemical germicides used in this procedure often correspond to the Environmental Protection Agency (EPA)- approved "hospital disinfectants" that are also "tuberculocidal." They are used commonly in laboratories for disinfection of laboratory benches and as part of detergent germicides used for housekeeping purposes.

iii) Low-Level Disinfection: This procedure kills most vegetative bacteria except *M. tuberculosis*, some fungi, and inactivates some viruses. The EPA approves chemical germicides used in this procedure in the US as "hospital disinfectants" or "sanitizers."

FDA, under the authority of the 1976 Medical Devices Amendment to the Food, Drug, and Cosmetic Act, regulates chemical germicides if they are advertised and marketed for use on specific medical devices (*e.g.*, dental unit waterline or flexible endoscope). A liquid chemical germicide marketed for use on a specific device is considered, for regulatory purposes, a medical device itself when used to disinfect that specific medical device. Also, this FDA regulatory authority over a particular instrument or device dictates that the manufacturer is obligated to

provide the user with adequate instructions for the safe and effective use of that device. These instructions must include methods to clean and disinfect or sterilize the item if it is to be marketed as a reusable medical device¹⁸. Hospital use disinfectants are ordinarily regulated by EPA under the Federal Insecticide Fungicide, Rodenticide Act, which is used by health care facilities to clean medical devices are considered to be medical devices themselves. These products, therefore, are also subject to regulation by the Food and Drug Administration. Which agency has primary authority depends on whether the product is deemed a critical, semi-critical, or non-critical device.

Critical and Semi-Critical Medical Devices: Liquid chemical cleaning agents properly used on critical or semi-critical medical devices are subject to the Food and Drug Administration's jurisdiction and regulations.

Authority: Food and Drug Administration (FDA).

Regulations: FDA, under the Federal Food, Drug and Cosmetic Act, codified at 21 CFR, requires that all chemical germicides used as sterilants and applied to critical or semi-critical medical devices must submit and have approved an FDA 510(k) premarket clearance.

A) Critical and Semi-Critical Devices: Critical devices are those which are introduced directly into the human body and which must be sterilized. Semi-critical devices are those who contact mucous membranes but do not penetrate the blood barrier and which should be sterilized.

B) Premarket Review: Before marketing and sale, all products used on critical and semi-critical devices must be approved by the FDA. Every manufacturer must submit a premarket approval application and data relating to the efficacy and effectiveness of the product.

C) Labeling: Products that fall under the jurisdiction of FDA should not contain EPA reference numbers (Registration/Establishment).

Non-Critical Medical Devices: EPA is primarily responsible for the premarket review of liquid chemical germicides that are intended for use on non-critical medical devices.

Authority: Environmental Protection Agency (EPA).

Regulations: Disinfectants used at health care facilities to disinfect noncritical devices are termed general purpose disinfectants and must be registered with EPA under the Federal Insecticide, Fungicide, and Rodenticide Act.

A) Non-Critical Devices: Defined as those devices that are used on medical equipment surfaces, including wheelchairs, and which should undergo intermediate or low-level disinfection.

B) Labeling: In addition to being subject to the general labeling requirements of 40 CFR 156, the label of disinfectant products intended for use on non-critical devices must contain the warning "not to be used as a terminal sterilant or high-level disinfectant."

Further, the label may not contain "mixed claims:" claims that suggest effectiveness as a general-purpose disinfectant and as a cleaner of critical and semi-critical medical devices.

C) Registration: EPA will only approve those products that meet efficacy and performance standards.

State Regulation: the Many States continue to regulate all antimicrobial and disinfectant cleaning products, whether intended for use on critical, Semi-critical or non-critical medical devices, as pesticide¹⁹. US biocide regulation is unique, and the registrations mechanism is based on product classification either by EPA or FDA. This gives the right direction to the manufacturers towards effective & innovative product delivery to the market.

European Union Regulation: Biocide products which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, are regulated by European Chemical Agency under the Biocidal Products Regulation (BPR). 'This regulation aims to improve the functioning of the biocidal products market in the EU while ensuring a high level of protection for humans and the environment. The BPR, Regulation (EU) 528/2012 adopted on 22 May 2012 and enforced from 1 September 2013, by

repeal the Biocidal Products Directive (Directive 98/8/EC).

Definition:

As per Directive 98/8/EC: “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”²⁰.

As per Article 3 (a) of Directive 528/2012: “Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action”.

“Any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action”²¹.”

The BPR maintains the two-stage regulatory approach-

1) Approval: Active substances are subject to an approval process at the EU level, the aim of which is to be included on an EU-approved list of active substances. That approval signals that the European Commission concluded after a peer review/risk assessment process that the active substance is sufficiently safe and efficacious, as set out in the BPR, to be made available and used on the EU market.

2) Authorization: The biocidal product must be authorized by the relevant Member states and competent authorities (MSCA) in whose territory it will be made available and used, or by the Commission (in case of a Union authorization). The granting of authorization is the signal that the biocidal product meets the requirements of the BPR as regards safety and efficacy and can be made

available and used in that Member State/the EU. The Biocidal Products Regulation (BPR) also sets rules for the use of articles treated with, or intentionally incorporating, one or more biocidal products. Articles can only be treated with biocidal products containing active substances approved in the EU. The definition of the biocidal active substance, biocidal products, and treated article are listed as follows:

Active Substance: A substance or a micro-organism that has an action on or against harmful organisms.

Biocidal Products: Any substance or mixture, consisting of, containing or generating one or more active substances, to destroy, deter, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Treated Article: Articles that have been treated with, or intentionally incorporating, one or more biocidal products.

Biocidal products are classified into 22 biocidal product-types, grouped in 4 main groups²². Pls. refer **Table 2** for detailed product classification-

Labeling Requirement: Biocide labeling requirement applicable to the articles treated with biocidal products containing active substances that have been approved in the EU. This rule also applies to imported articles. Companies are also required to provide the consumers with information about the biocidal treatment of the article they are selling. The BPR requires manufacturers and importers of treated articles to label treated articles when:

- A claim that the treated article has biocidal properties is made.
- It is required in the conditions of the approval of the active substance contained in the biocidal product used to treat the article.

The labeling of treated articles must be done according to Article 69 of 528/2012 Directive, Directive 2000/54/EC, Directive 1272/2008, Directive 1999/45/EC, and the additional requirements in the Biocidal Products Regulation.

TABLE 2A: BIOCIDAL PRODUCT CLASSIFICATION

Number	Product-type	Description
Main group 1: Disinfectants- These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders, and similar products		
PT 1	Human hygiene	Products in this group are biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp
PT 2	Disinfectants and algaecides not intended for direct application to humans or animals	Used for the disinfection of surfaces, materials, equipment, and furniture which are not used for direct contact with food or feeding stuff. Usage areas include, among other things, swimming pools, aquariums, bathing, and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and other areas for professional activities Used for disinfection of air, water not used for human or animal consumption, chemical toilets, wastewater, hospital waste, and soil Used as algaecides for treatment of swimming pools, aquariums, and other waters and remedial treatment of construction materials Used to be incorporated in textiles, tissues, masks, paints and other articles or materials to produce treated articles with disinfecting properties.
PT 3	Veterinary hygiene	Used for veterinary hygiene purposes such as disinfectants, disinfecting soaps, oral or corporal hygiene products or with anti-microbial function Used to disinfect the materials and surfaces associated with the housing or transportation of animals
PT 4	Food and feed area	Used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed (including drinking water) for humans and animals Used to impregnate materials which may enter into contact with food
PT 5	Drinking water	Used for the disinfection of drinking water for both humans and animals

TABLE 2B: BIOCIDAL PRODUCT CLASSIFICATION

Number	Product-type	Description
Main group 2: Preservatives- Unless otherwise stated these product-types include only products to prevent microbial and algal development		
PT 6	Preservatives for products during storage	Used for the preservation of manufactured products, other than foodstuffs, feeding stuff, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life
PT 7	Film preservatives	Used as preservatives for the storage or use of rodenticide, insecticide or other baits. Used for the preservation of films or coatings by the control of microbial deterioration or algal growth to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, artworks
PT 8	Wood preservatives	Used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms, including insects. This product type includes both preventive and curative products
PT 9	Fibre, leather, rubber and polymerized materials preservatives	Used for the preservation of fibrous or polymerized materials, such as leather, rubber or paper or textile products by the control of microbiological deterioration This product-type includes biocidal products which antagonize the settlement of micro-organisms on the surface of materials and therefore hamper or prevent the development of odor and offer other kinds of benefits
PT 10	Construction material preservatives	Used for the preservation of masonry, composite materials, or other construction materials other than wood by the control of the microbiological and algal attack
PT 11	Preservatives for liquid-cooling and processing systems	Used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae, and mussels Products used for the disinfection of drinking water or of water for swimming pools are not included in this product-type
PT 12	Slimecides	Used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g., on wood and paper pulp, porous sand strata in oil extraction
PT 13	Working or cutting fluid preservatives	Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials

TABLE 2C: BIOCIDAL PRODUCT CLASSIFICATION

Number	Product-type	Description
Main group 3: Pest control		
PT 14	Rodenticides	Used for the control of mice, rats or other rodents, by means other than repulsion or attraction
PT 15	Avicides	Used for the control of birds, by means other than repulsion or attraction.
PT 16	Molluscicides, vermicides, and products to control other invertebrates	Used for the control of mollusks, worms, and invertebrates not covered by other product types, by means other than repulsion or attraction
PT 17	Piscicides	Used for the control of fish, by means other than repulsion or attraction.
PT 18	Insecticides, acaricides, and products to control other arthropods	Used for the control of arthropods (e.g., insects, arachnids and crustaceans), by means other than repulsion or attraction
PT 19	Repellents and attractants	Used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds, fish, rodents), by repelling or attracting, including those that are used for human or veterinary hygiene either directly on the skin or indirectly in the environment of humans or animals
PT 20	Control of other vertebrates	Used for the control of vertebrates other than those already covered by the other product types of this main group, by means other than repulsion or attraction

TABLE 2D: BIOCIDAL PRODUCT CLASSIFICATION

Number	Product-type	Description
Main group 3: Other biocidal products		
PT 21	Antifouling products	Used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water
PT 22	Embalming and taxidermist fluids	Used for the disinfection and preservation of human or animal corpses, or parts thereof

It is very important to categorize the product to determine whether BPR regulation applies or not. BPR regulation does not apply to preservatives used in cosmetics and food because such uses are not covered by above product types. A treated article that has a primary biocidal function shall be considered a biocidal product. Europe regulations are very precise and clear to understand the Product classification, registration requirement of each category, which helps industry and authority for rapid approvals and fastest delivery to market which benefits consumers and social economy of the region.

India Regulation: India Disinfectant market is the fastest growing market in the world and stepping towards the top five revenue-generating economy in the Surface disinfectant category.

This represents a positive for the industry, and the nature of the regulatory environment that is emerging provides further grounds for optimism. Disinfectant legislation is governed by the Drugs and Cosmetics Act, and the legislative body is CDSCO (Central Drugs Standards Control Organization) headed by Drugs controller general of India.

As per the Drugs and Cosmetics Act; Disinfectants are –

“Such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of [vermin] or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette²³.”

By virtue of Drug definition, Disinfectants are recognized as Drug in India and all regulation applicable to drugs follows for disinfectants. Manufacturing is enforced by state licensing authorities under the rules of part VII and compliance to schedule M requirements of Drugs and Cosmetics Act and Import is regulated *via* CDSCO under the rules of part IV of Drugs and Cosmetics Act. Sale license requirement is exempted under Schedule K (12) of Drugs and Cosmetics Act, in fulfillment to the condition (17) of Rule 65. Product Claims are regulated through Schedule J, Drugs, and Magic Remedies (Objectionable Advertisements) Act and Advertising Standards Council of India (ASCI).

Product standards are classified under Schedule 'O' and colors are permitted under Rule 127 & Schedule Q of Drugs and Cosmetics Act.

Labeling requirement is governed by Schedule 'O' and rule 96 of Drugs and Cosmetic Act, as follows-

- The name of the product (Trade Name)
- Generic Name (Proper name)
- The name and full address of the manufacturer
- The full formula or list of ingredients of the preparation
- Date of manufacture
- Date up to which the product can be used
- Batch Number
- Manufacturing license number
- Quantity present in the container
- Indications and mode of use
- Importer name and address details (if import)
- Import Registration No. (in case of Imports)

Addition to D & C labeling requirement, Legal Mandate²⁴ is to cover the following information:

- Consumer care & registered office details
- Month and year of import (if import)
- MRP (Inclusive of all taxes)

- Font size and area – As per Rule 7 to 9 of LM Act

On the other side, Medical Device Rules 2017 of Drugs and Cosmetics Act, classify disinfectants as Class 'B' Medical Device based on the intended use as-

1. The sterilization of any other medical device.
2. The end-point disinfection of any other medical device.
3. The Disinfection, Cleaning, rinsing or Hydration of contact lenses²⁵.

Products categorized under medical device classification having a separate set of Regulation, compliance, and labeling requirements under Medical Device rules 2017.

Disinfectant regulations in India don't differentiate Drug (Medicinal Product) and Disinfectants (Surface disinfectants) separately. Disinfectants are treated as Drugs, and all rules as applicable to Drugs implies to Disinfectants as well. The registration requirement is common for Drug and Disinfectants, unlike US and EU markets.

Hence, there is a need for the regulatory framework of surface disinfectants, *i.e.* reclassification and categorization similar to US and EU markets unlike drug and medical devices.

TABLE 3: COMPARATIVE TABLE OF THE IDENTIFIED KEY ASPECTS OF SURFACE DISINFECTANTS THROUGHOUT THE REGULATORY FRAMEWORK

Country	United States	Europe	India
Product Classification	Antimicrobial Pesticides	Biocidal Products	Disinfectants
Regulating Body	EPA	ECHA	CDSCO
Applicable Laws	FIFRA	Biocide products regulation Directive 528/2012	D & C Act Legal Metrology Act
Labelling Requirement	40 CFR 156	Article 69 of 528/2012 Directive. Directive 2000/54/EC Directive 1272/2008 Directive 1999/45/EC	Schedule O of D & C Act Rule 96 of D & C Act Legal Metrology Act
GMP Requirement	Not Applicable	Not Applicable	Schedule M of D & C Act

EPA - United States Environmental Protection Agency. FDA – Food & Drug Administration. ECHA - European Chemicals Agency. CDSCO – Central Drugs standards Control Organization. FIFRA - Federal Insecticide, Fungicide and Rodenticide Act. D & C Act – Drugs and Cosmetics Act. CFR - Code of Federal Regulations.

CONCLUSION: The present review of regulations is not comprehensive but rather an attempt to give an idea about the complexities of this area. We have seen three major countries regulatory frameworks and examined good and

valid examples of different aspects included in the laws that control and limit the Biocide industry. Throughout this review, there has been a conscious effort to scale down a subject which is far from being brief, and all the effort has been put into

being able to provide a wide vision of what the global scheme of regulations that affect directly or indirectly to all disinfectant products. There is a need for regulatory experts to work hand in hand to harmonize the regulations with Global standards, which can overcome the Industry challenges and makes a significant social and economic contribution to the nation. Law is a law after all, and it is mainly based on the abilities and competencies derived from the Legislation and Deontology scope. The direct application of the analysis of these laws correlates perfectly with the private sector and biocide industry, both with its merits and challenges.

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