



Welcome

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Biocides



BIOCIDES and Consumer Products

Biocides and Consumer Products: Reviewing Treated Articles in the EU, US and Canada



Biocides

Agenda

- Definitions
- Classifications
- Consumer Products
- EU
- US
- Canada
- Summary
- Worldwide Regulations



Biocides

Definitions

- A biocide is defined as an active chemical molecule that controls the growth of or kills a specific organism, i.e. bacteria. In some cases an item may be treated with a specific biocide, such as insecticide, in order to repel insects. (EU)
- A pesticide is defined as any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, or any nitrogen stabilizer. (US)
- Biocidal product is 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.
- Treated article, it's an item that has been manufactured with a specific type of biocide to protect that item from staining, bad odor, or premature material degradation caused by microbial or bacterial growth.

Biocides

What are biocides?

- Insecticides
- Rodenticides
- Pesticides
- Algicides
- Fungicides
- Slimicides
- Herbicides
- Avicides
- Bactericides



Biocides

Biocide classifications

- Country Dependent
- The EU, US and Canada each have 4 main groupings that classify types of biocide. However, each country utilizes a different classification system.



Biocides

Classifications

Biocides

European Union

- Disinfectants (5)
- Preservatives (8)
- Pest control (7)
- Other biocidal products (2)

Pesticides

United States

- Conventional pesticides
- Antimicrobial pesticides (12)
- Biopesticides (3)
- Inert ingredients

Pesticides

Canada

- Domestic class
- Commercial class products
- Restricted products
- Manufacturing - Pesticides or products regulated under the Feeds Act or Fertilizers Act.

Biocides

Treated Articles

Treated article, it's an item that has been manufactured with a specific type of biocide to protect that item from staining, bad odor, or premature material degradation caused by microbial or bacterial growth.

- When we discuss various microbial activity its important to understand that microbes are microscopic organisms that exist as unicellular, multicellular, or cell clusters. Microorganisms can be classified into six major types: bacteria, archaea, fungi, protozoa, algae, and viruses. There is also a seventh classification helminths (round/flat worms) which is not technically a microorganism but does live part of its lifecycle in a microscopic form.
- Antimicrobial properties enhance the performance and lifespan of consumer products. In fabrics, the formation of unpleasant odors is reduced resulting in pleasant and fresh smell to the item even after use. Antimicrobial agents can be manufactured into a range of materials including plastics, coatings, textiles and many more. Kitchen fixture stays cleaner longer and prevents harmful microbial growth on surfaces.

Biocides

Historical Usage of Textile Preservation

- The Egyptians began the science of textile preservation through the use of various spices and herbs to preserve mummy wrappings.
- The Chinese later used bamboo, containing an antimicrobial substance, bamboo-kun, in housing design and construction.



- In the 1940's military organizations used antimicrobials such as chlorinated waxes, copper and antimony salts to prevent textiles from rotting. Products such as tents, tarpaulins, and truck covers
- Present Day- what aren't we using biocides on.



Biocides



Biocides

Types of treated articles

- Building Materials (wood, plastic, paints, adhesives, caulks, etc..)
- Cleaning Products
- Computer peripherals (i.e. keyboards/mice)
- Consumer Flooring
- Door Hardware
- Food Storage containers
- Home Appliances (washer seals, refrigerator/freezer seals)
- Kitchenware
- Light switches
- Medical products (i.e. hospital gowns, patient clothes, curtain, bed cover, etc.)
- Paint
- Pet Products
- Pool & Spa Products
- Soaps and Lotions
- Sporting Goods & Exercise Equipment
- Textiles
- Travel Accessories

Biocides

Biocide Manufacturers

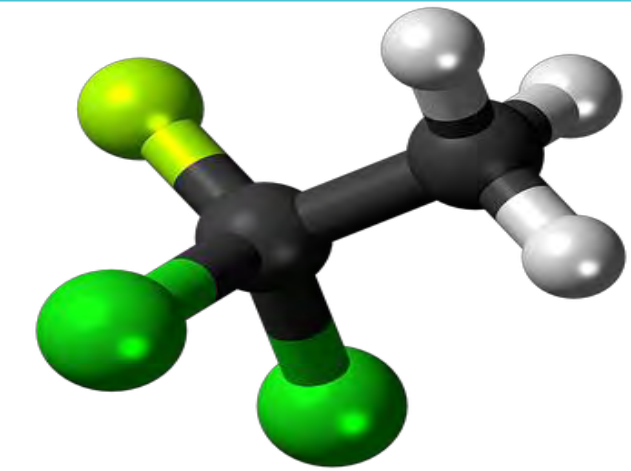
- The Dow Chemical Company
- Lonza Group Ltd
- BASF SE
- Croda International Plc
- Clariant AG
- Biocote
- Verital
- Microban
- Kemin
- Akzo Novel N.V.
- Evonik Industries A.G.

Commercial Biocides

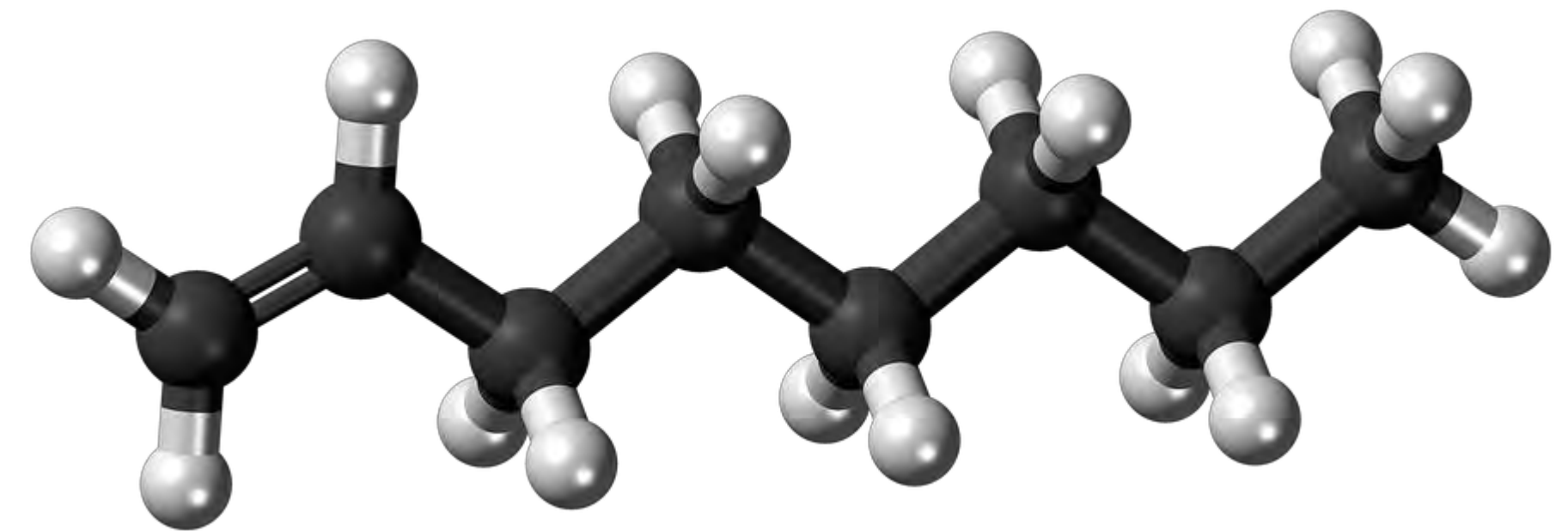
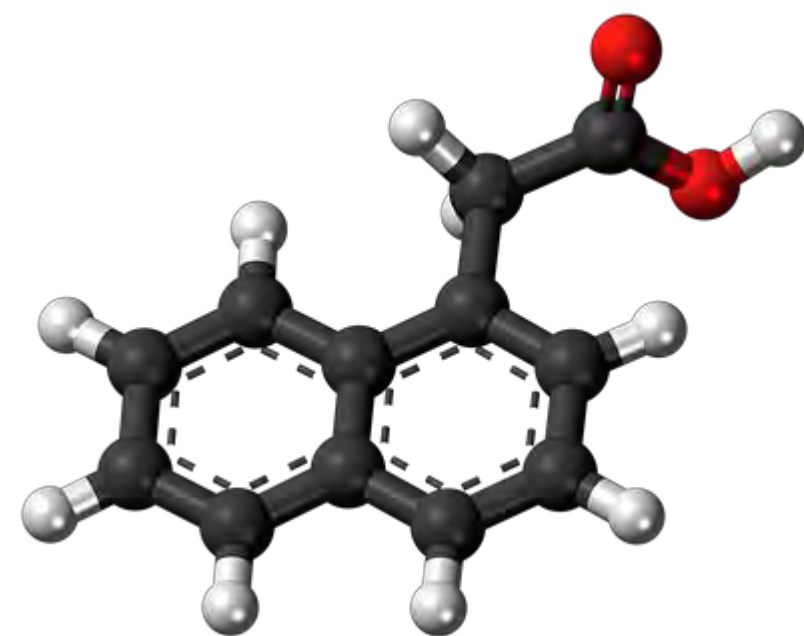
- Irgaguard 1000- BASF (Ciba) Finishing agent based - on triclosan
- Irgasan -Sigma Aldrich Finishing agent - based on triclosan
- Microban Microban International Agent - based on triclosan
- Silvadur- The Dow Chemical Company - Interpenetrating polymer network with silver ions
- Saniguard Nano-ZN L.N.Chemical Industries Finishing solution based on an aqueous nano-dispersion of zinc oxide

Biocides

Regularly used biocides in the textile industry



- Silver, quaternary ammonium compounds, triclosan, metal salts, or even natural polymers, organo-copper compounds, organo-tin compounds, and chlorinated phenols.
- Copper naphthenate and copper-8-hydroxyquinolate are multipurpose biocides, specifically against fungi, bacteria, and algae. These compounds used to prevent deterioration of textiles i.e., cotton and flax canvases, awnings, tarpaulins, tents, outdoor sporting apparel and gear that are exposed to soil and/or extreme weather conditions.



Biocides

Triclosan is an organic compound known as a diphenyl ether, currently banned in soaps and hand sanitizers by the US FDA.

By 2024 antimicrobial's ingredient usage and sales is expected to increase from 5 to 7 billion dollars/year.

A large amount of growth is expected in the cosmetics and personal care products in preservative applications sector and especially in South America.



European Union

Biocides

Legislation

- Biocidal Products Regulation ((EU) No 528/2012 (BPR))



Responsible Agency(ies)

- European Chemicals Agency (ECHA), Member state agencies, i.e. HSE- UK, Sweden - Swedish Chemicals Agency (KemI) , Germany- Federal Institute for Occupational Safety and Health (“Bundesanstalt für Arbeitsschutz und Arbeitsmedizin” – BAuA).

Biocides

Approved Biocides

In the EU a list of approved biocides is maintained by the European Chemicals Agency (ECHA). A biocidal product is not able to be placed on the EU market if the active substance supplier or product supplier is not listed in the active substance suppliers list, which is also called Article 95 list. Biocidal substance authorizations are done on a case by case basis and cannot exceed 10 years but may be renewed.

According to the database on approved substances (Annex I of the BPR), as of 9/1/2020 there are:

- 884 active substances
- 4832 biocidal products
- 4682 manufactures

Biocides

Classifications

The Biocidal Products Regulation BPR regulates 22 different product type (PT) of biocides across 4 categories. The 4 categories are:

- Main Group 1: Disinfectants
 - Human hygiene, Disinfectants and algaecides, Veterinary hygiene, Food and feed area, Drinking water
- Main Group 2: Preservatives
 - Preservatives, Film preservatives, Wood preservatives, Fibre, leather, rubber and polymerised materials preservatives, Construction material preservatives, Preservatives for liquid-cooling and processing systems, Slimicides, Working or cutting fluid preservatives

Biocides

Classifications(Cont'd)

- Main Group 3: Pest control
 - Rodenticides, Avicides, Molluscicides, Piscicides, Insecticides, Repellents or attractants, Control of other vertebrates
- Main Group 4: Other biocidal products
 - Antifouling products, Embalming or taxidermist fluids

Biocides

Treated Articles

Under the BPR, Article 58, a 'treated article' is defined as any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.

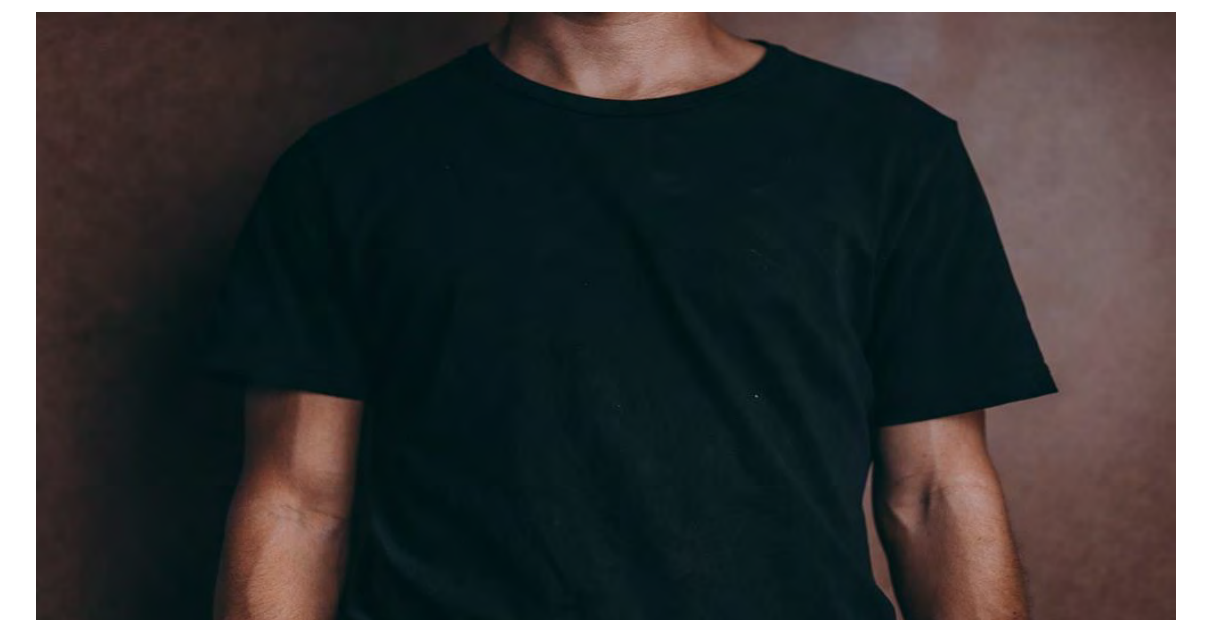
Treated articles are divided in three categories depending on their reference to active substances and their biocidal properties:

- Treated articles with no claim or reference to biocidal properties
 - Water-based inks and varnishes, as well as of many water-based fountain solutions and cleaning agents for offset printing utilize antimicrobial compound in order to prevent microbiological growth and contamination.

Biocides

Examples

- Treated articles with a claim referring to biocidal properties,
 - For textiles treated with silver for antibacterial purposes. A T-shirt which is treated with a biocidal product to protect the product from bacterial attack is considered an article treated with biocides.
- Treated articles with no reference to biocidal properties but with approved active substances and related labelling requirements.
 - Laundry detergent containing preservative which is a skin sensitizer, requires labeling regarding the sensitizer.



Biocides

Labeling /Claims Requirements

If you make biocidal claims for the article, it may have to carry a label with information about the biocide that was used. The BPR requires manufacturers and importers of treated articles to label the treated articles when:

- a claim that the treated article has biocidal properties is made. i.e. *Contains a preservative to control microbiological deterioration.*
- it is required in the conditions of the approval of the active substance contained in the biocidal product used to treat the article.

Manufacturers and importers of treated articles have to make sure that products are correctly labelled. The label should be easy to read, visible and in the national language of the Member State of introduction.

Biocides

When a treated article is placed on the market and it refers to the biocidal properties of the active substances within it, the label also has to contain:

- a statement that the treated article incorporates biocidal products;
- the biocidal property attributed to the treated article;
- the names of the active substances;
- if present, the names of each biocidal (nano-) substance followed by the word 'nano' in brackets; and
- any relevant instructions for use.

Note: Regulations have binding legal force throughout every Member State and enter into force on a set date in all the Member States. Directives lay down certain results that must be achieved but each Member State is free to decide how to transpose directives into national laws.

United States

Biocides



Legislation

- The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires the registration of any substance intended to prevent, destroy, repel, or mitigate pests.
- Federal Food, Drug, and Cosmetic Act (FD&C Act)

● **Responsible Agency(ies)**

- While the US EPA has responsibility for registration of pesticide substances there is crossover jurisdiction with the FDA for compounds used in food, drugs and cosmetic products, as well as medical devices. The responsibilities of each agency have been clarified in various Memorandums of Understanding (MOU's) between the 2 agencies.

Biocides

Approved Substances

FIFRA currently lists 2905 substances in their chemical search database, 808 of which are classified as antimicrobials. EPA is reviewing each registered pesticide every 15 years to determine whether it still meets the FIFRA standard for registration



Biocides

Classifications

The EPA classifies and registers pesticides into 4 categories.

- Conventional pesticides
- Antimicrobial pesticides
 - (Agricultural Premises and Equipment, Food Handling/Storage Establishments, Premises, and Equipment, Residential and Public Access Premises, Medical Premises and Equipment, Human Drinking Water Systems, Materials Preservatives, Industrial Processes and Water Systems, Antifouling coatings, Wood Preservatives, Swimming Pools, Aquatic Areas

Biocides

Classifications (Contd.)

- Biopesticides
 - microbial pesticides,
 - plant-incorporated protectants, and
 - biochemical pesticides
- Inert ingredients



Biocides

Treated Articles

- The term "treated articles" is defined as items that are treated with an antimicrobial pesticide to protect the item itself. The pesticides are usually added to the products (e.g., plastic shower curtain) during manufacture; however, they may be added after manufacture but before use of the article (e.g., incorporation of a pesticide in paint).
- These treated products often claim to protect the public against harmful microorganisms. These fall into a regulatory category of implied or explicit public health pesticidal claims.



Biocides

EPA grants the treated articles exemption for a non-public-health use of a pesticide that is intended to protect only the treated article or substance itself. Consumers may distinguish such products by the absence of the EPA's pesticide registration number of the registered pesticide used for protecting the article itself.

Known as the "Treated Articles Exemption," 40 CFR section 152.25(a) provides an exemption from all requirements of FIFRA for qualifying articles or substances treated with, or containing a pesticide, if:

- (1) the incorporated pesticide is registered for use in or on the article or substance, and;
- (2) the sole purpose of the treatment is to protect the article or substance itself.

To qualify for the treated articles exemption, both conditions stated above must be met. If both are not met, the article or substance does not qualify for the exemption and is subject to regulation under FIFRA.

Biocides

Labeling /Claims Requirements

- All registered pesticide products must display labels that show the following information clearly and prominently:
 - Name, brand, or trademark product sold under
 - Name and address of the producer or registrant
 - Net contents
 - Product registration number
 - Producing establishment's number
 - Ingredient statement
 - Warning or precautionary statements
 - Directions for use

Biocides

Claims

- A product that incorporates an antimicrobial pesticide, but does not make claims about antimicrobial effect, is not regulated under FIFRA, but is instead subject to reporting requirements under the Toxic Substances Control Act (TSCA).
- A product whose label includes public health claims, such as "prevents bacterial growth", is required to satisfy the Act's requirements and must display an EPA-approved product label..
- A product that does make a claim about antimicrobial effects – such as "contains a preservative" – on the product itself, falls under FIFRA's treated articles exemption. To meet the Treated Articles exemption labeling requirements, the product label may only bear claims that the product itself is protected by the pesticide. For example, a claim must make clear that the article has been treated with the antimicrobial product to protect the *product* from the growth of microbes.

Canada

Biocides



Legislation

- The Pest Control Products Act requires that all pest control products be assessed as to their safety, merit, and value. The intent of the legislation is to ensure the acceptability of the risks, safety, merit and value of pest control products used in Canada.

Responsible Agency(ies)

- Health Canada's Pest Management Regulatory Agency (PMRA). Canada's regulatory system allows for federal, Provincial and municipal regulations.

Biocides

Approved Substances

The total number of active ingredients registered for use in Canada has increased from approximately 560 in 2007 to 658 towards the end of 2018. The overall number of registered products increased from approximately 5505 to 7707 between 2007 and March 2019, despite the removal of many older products. 884 of the products are designated as Material Preservatives.

Of those 658 active ingredients 51 are designated as antimicrobial. As of 8/30/2020 the PMRA has 5236 registered antimicrobial products utilizing 51 antimicrobial active ingredients that manufacturers can consider using when treating an article.

Pesticides are required to be reviewed every 15 years in order to maintain their legality. As new information becomes available any pesticide may be removed from the list.

Biocides

Classifications

Pesticides have been classified into 4 main groups:

- Domestic class
- Commercial class products
- Restricted products can only be used under certain circumstances by specially trained individuals.
- Manufacturing - Pesticides or products regulated under the Feeds Act or Fertilizers Act.



Biocides

Treated Articles

Treated articles are defined as a pest control product under the Pest Control Products Act. The antimicrobial preservative used to treat the article, is always required to be registered under the Pest Control Products Act; however, the PMRA will not require the registration of some articles treated with an antimicrobial preservative, if they meet certain criteria. Even though some articles may be exempt from registration (including documentation and renewals), they are still subject to regulatory oversight.

Treated articles that require registration

If a pesticide has been incorporated into or applied to an article in order for the article to act as a delivery mechanism for the pesticide, the pesticide (for example, insecticide) and the treated article (for example, clothing) must each be registered as a pest control product under the Pest Control Products Act. In this example, the clothing acts as a delivery mechanism for the pesticide when it is treated with an insecticide to repel mosquitoes or ticks.

Biocides

Treated articles that require registration of the pesticide only

If a pesticide has been incorporated into or applied to an article in order to provide a benefit to the product itself (in other words, preservation) the pesticide (in other words, the antimicrobial preservative) must be registered under the Pest Control Products Act for that specific use. In this case, the PMRA will not typically require the registration of the treated article itself.



Biocides

Labeling /Claims Requirements

- Trade or Product Name
- Classification
- Pesticide Type
- Active Ingredient(s) and Guarantee of Concentration
- Type of Formulation
- Pest Control Product Registration Number
- Registrant's Name and Address
- Net Contents of Package
- Directions for Use
- Degree and Nature of Hazards
- Precautionary Statements and Handling Precautions
- Pesticides labels are required to carry the following information:
 - First Aid Instructions
 - Toxicological Information
 - Notice to user

Biocides

Labeling (Contd.)

An antimicrobial treated article must be labelled with clear and easily understandable information for the consumer. This applies to all articles which are:

- sold with a claim that the article has a specific function and
- treated with an active substance that require labelling according to the approval of the substance.

The treated article should also be labelled with relevant instructions for use, including precautions, if this is necessary to protect humans, animals, and the environment.

Biocides

Claims

- Claims on articles treated with an antimicrobial preservative are limited to the effect of the antimicrobial preservative used to treat the articles. As per section 6 of the Pest Control Products Act, any misleading marketing claims that do not accurately reflect the purpose of the antimicrobial treatment are not permitted.
- Claims such as "antimicrobial" and "preservative" cannot be used alone and must be properly qualified. A properly qualified claim would be similar to the following:

"Treated with an antimicrobial that provides mildew-resistant dried paint coating".

"This article has been treated with an antimicrobial agent to control odours."

Comparisons

Biocides

The EU has a more stringent safety threshold than the US or Canada, the pesticide industry in the US has only to demonstrate that its products “will not generally cause unreasonable adverse effects on the environment,” which is partially defined as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.

While the EU and Canada both follow the “precautionary principle”, regulation of safety even if evidence is incomplete or speculative. Also known as better safe than sorry. Canada, however, has sometimes reached different conclusions on the hazards of certain pesticides. The EU prohibits the use of a number of active substances in pesticides that are authorized in Canada.

The US and Canada require pesticides be reviewed every 15 years, the EU at least every 10 years. These schedules are all subject to change based on new scientific understanding and information.

Biocides

The EU BPR legislation specifically exempts products covered under separate directives or regulations (i.e. food, cosmetics, toys etc..) and leaves enforcement to each member states designated agency.

The United States and Canada regulations utilize multiple jurisdictional agreement (Memorandums of Understanding (MOU's) between agencies. The US EPA has primary responsibility but has some crossover with the Food and Drug Administration depending on the product (Food/medical/cosmetics).

In Canada, the federal departments of Agriculture Canada, Environment Canada, and Health and Welfare Canada coordinate the regulation of pesticides. Pesticide regulation is also under the shared authority of the federal, provincial, territorial governments as well as municipal entities.

Worldwide Biocide Legislation

Biocides

Other countries with biocide legislation:

- [China](#)
- [Japan](#)
- [MERCOSUR \(cleaning solutions only\)](#)
 - [Argentina](#)
 - [Brazil](#)
 - [Paraguay](#)
 - [Uruguay](#)
- [New Zealand](#)
- [South Korea](#)
- [Trinidad/Tobago](#)

Note: each country legislates products differently





Thank You

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