

Dossier – Biocides and food contact materials

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1 Definition of biocides

Biocides are chemical substances or microorganisms that are applied to kill living organisms. Alternatively, biocides can be used to suppress harmful properties or control the growth of organisms. They aim to protect different organisms (e.g. animals, humans, plants) or also products (e.g. food, wood, drinking water) from being negatively affected by the organisms in question. Biocides are classified by their target organism as e.g. bacteriocides, fungicide, herbicides, insecticides, and rodenticides. In contrast, disinfectants act only against microorganisms and are exclusively used on surfaces. The term pesticide is often used with a similar meaning. It refers to chemicals or other agents that protect organisms (e.g. plants, animals, humans) from nuisance or diseases caused by other organisms (e.g. microorganisms, nematodes). In general language use, the term pesticide is often misleadingly treated as synonymous with more specific terms such as insecticides or plant protection products.

There are slight differences between the general and legal definitions of these terms with latter requiring a precise use. Under European legislation, *biocides* are defined as “chemicals used to suppress organisms that are harmful to human or animal health, or that cause damage to natural or manufactured materials” [1]. *Plant protection products* are excluded under this definition, because they specifically refer to substances protecting plants from damaging influences. In the U.S., biocides are rather named *antimicrobial substances*, which are regulated either as *food additives* or *pesticide chemicals*.

2 Relevance of biocides in FCMs

Biocides are commonly applied to reduce the number of microorganisms on the food itself and on any material coming into contact with the food. Other commonly used methods reducing the cell count on food and food contact materials (FCMs) include heat treatment, acidification, and irradiation. In contrast, cooling decreases and freezing stops the growth of microorganisms, but they are not killed under these conditions.

During food processing and storage, the eradication of microorganisms serves two main purposes: the prevention of food-borne illnesses and spoilage. Perishable food including meat, dairy products, ripe fruits, fish and seafood is especially susceptible to contamination with pathogenic and non-pathogenic microorganisms. Thus, special care has to be taken when handling these food items.

In the context of disease prevention, a reduction in the number of microorganisms is desirable, as an infectious dose usually has to be exceeded for disease outbreaks. In the U.S., food-borne illnesses are mainly caused by the microorganisms norovirus, nontyphoidal *Salmonella*, *Clostridium perfringens*, *Campylobacter* ssp. and *Staphylococcus aureus* [2]. These pathogens mainly cause gastrointestinal infections, which may be of differing severity. During the last century the spectrum of food-borne illnesses has changed. Previously also severe infectious diseases such as typhoid fever, tuberculosis and cholera were commonly transferred via food and water. However, better hygiene has strongly decreased the incidence of these diseases in industrialized countries in the course of the 20th century.

The second reason for the application of biocides is the prevention of food spoilage which causes significant economic damage at all stages of the food production chain. Spoilage is one reason why one third of all food produced in Switzerland is wasted and not consumed [3].

3 Classes and applications of biocides

3.1 Examples and mechanisms of action

Widely applied biocides include alcohols, organic acids and their esters, aldehydes, amines, quarternary ammonium compounds (QATs), halogen compounds, ionic silver and nanosilver, oxidizing agents, isothiazolones, phenols and biguanides (Table 1, Figure 1). All these groups of biocides are also used in FCM-related areas [4].

Table 1. Classes of biocides

Group	Examples ^a	Main target
Alcohols	<ul style="list-style-type: none"> Ethanol 2-Propanol 2-Phenoxyethanol 	<ul style="list-style-type: none"> Membrane uncoupler Protein denaturation
Aldehydes	<ul style="list-style-type: none"> Glutaraldehyde Formaldehyde Glyoxal 	<ul style="list-style-type: none"> Cell wall Protein denaturation
Amines	<ul style="list-style-type: none"> Diethylamine Glucoprotamin 	<ul style="list-style-type: none"> Cell wall Cytoplasmic membrane
Biguanides	<ul style="list-style-type: none"> Polyhexamethylen-biguanid (PHMB) 	<ul style="list-style-type: none"> Cytoplasmic membrane
Halogen compounds (oxidizing)	<ul style="list-style-type: none"> Sodium hypochlorite Chlorine dioxide Calcium hypochlorite 	<ul style="list-style-type: none"> Nucleic acids
Isothiazolinones	<ul style="list-style-type: none"> Chlormethylisothiazolinone / Methylisothiazolinone (CMIT/MIT) 	<ul style="list-style-type: none"> Inhibition of key enzymes
Organic acids and esters	<ul style="list-style-type: none"> Parabens Propionic acid Formic acid Benzoic acid Salicylic acid 	<ul style="list-style-type: none"> Cytoplasmic membrane Transport inhibition
Oxidizing agents	<ul style="list-style-type: none"> Hydrogen peroxide Sodium persulfate 	<ul style="list-style-type: none"> Nucleic acids
Phenolics	<ul style="list-style-type: none"> Triclosan 	<ul style="list-style-type: none"> Cytoplasmic membrane Inhibition of key enzymes
Quarternary ammonium compounds (QATs)	<ul style="list-style-type: none"> Benzalkonium chloride (ADBAC) Didecylidimethylammoniumchlorid (DDAC) 	<ul style="list-style-type: none"> Cell wall Cytoplasmic membrane
Silver compounds	<ul style="list-style-type: none"> Silver and silver zeolite Nanosilver 	<ul style="list-style-type: none"> Enzymes

^aAll examples are under review for authorization as biocides in the food and feed area (PT4) of the European Biocidal Product Regulation.

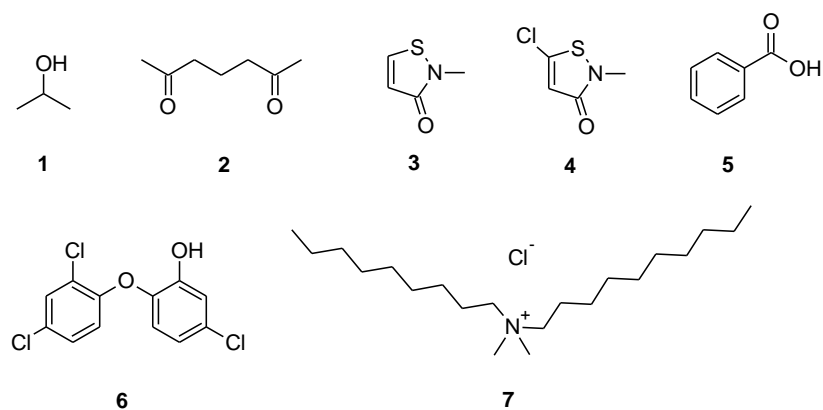


Figure 1. Chemical structures of biocides: 2-propanol 1, glutaraldehyde 2, MIT 3, CMIT 4, benzoic acid 5, triclosan 6, and DDAC 7.

Often biocidal products contain mixtures of chemicals with different mechanisms of action. Some biocides are membrane-active agents and thus destroy the envelope of the cells (Table 1) [5-7]. Others react with functional groups of proteins and/or nucleic acids and as a result inhibit metabolism and cell growth.

3.2 Process biocides

In the context of FCMs process biocides are used to prevent microbial contamination during the production of the materials, but also to disinfect or sanitize an FCM surface before it comes into contact with food. A few examples of the application of process biocides are listed here:

- Slimicides are commonly used in paper production to prevent the formation of biofilms [8]. Mainly oxidizing agents, e.g. chlorine dioxide and sodium hypobromite, have been reported to be used as slimicides [8, 9].
- Echeverry and colleagues validated intervention strategies to prevent microbial contamination of beef. The authors illustratively described the procedure of equipment cleaning using different QAT solutions [10].
- Lee et al. compared the performance of three process biocides in the disinfection of low density polyethylene (LDPE) films, metal cans and an aseptic packaging machine [11]. They showed the efficacy of all three biocidal products when applied in the cleaning of the commercial packaging machine.

3.3 Surface biocides and biocides in active packaging

According to article 3 of Commission Regulation (EC) No 450/2009 active food packaging is used with the intention “to extend the shelf-life or to maintain or improve the condition of the packaged food” and it is “designed to deliberately incorporate components that would release or absorb substances into or from the packaged food or the environment surrounding the food” [12].

Biocides are incorporated in such active materials with the intention to be released into the food or to act on the surface of the food product. In the scientific literature of the past years many highly specific biocidal applications were described. In the following we list some examples of active packaging containing biocides.

- Martínez-Abad and colleagues published a study on silver-containing and beeswax coated polylactide films. The thickness of the coating controlled the release rate of silver into the food or food simulant. Bacterial growth was found to be inhibited by this kind of active packaging [13].
- In 2011, the protease subtilisin was immobilized on polycaprolactone and its effect on microbial growth was

investigated. The microbial contamination of meat samples stored in this active packaging was reduced, while the cell count of control samples increased over the same time [14].

- In 2013, Liu et al. incorporated bionanocomposites, composed of the two natural polymers chitosan and cellulose, and the biocide benzalkonium chloride in alginate films, [15]. The inclusion of the bionanocomposites into the alginate polymer improved the mechanical and biocidal properties of the material.
- The controlled release of the strongly oxidizing, gaseous agent ClO_2 from active packaging materials was described in two illustrative studies. Ray and colleagues incorporated sodium chlorite and citric acid into polylactide acid films. Moisture originating from the packaged product (e.g. any fresh produce) was able to catalyze the formation of ClO_2 which then acted as biocide on the surface of the product [16]. Li and colleagues described a coating in which ClO_2 was polymer-encapsulated in a water-oil-water double emulsion [17]. Within 28 days 30% of the biocidal gas was released from the coating and killed different bacterial species.
- Lahmer and colleagues investigated the antimicrobial activity of arginine-chitosan derivatives, water-soluble, modified polymers based on a natural glucosamine. They suggested the inclusion of the derivatives in packaging materials or their use as coating to prevent microbial growth in meat juice [18].
- Jin et al. provided a delivery system for the antibacterial peptide nisin that was based on polylactide. The authors could prove antibacterial activity especially against gram-positive bacteria when nisin was released from the polylactide films [19].
- Amphiphilic QATs were incorporated into hydrophilic polyurethane resins. The biocides concentrated at the polymer-air interface. Hereupon, the material exhibited antibacterial function. Moreover, no migration of QATs from this active material was measured by high-pressure liquid chromatography and bioassays [20].
- Muranyi and colleagues coated glass with titanium dioxide and showed antimicrobial properties after irradiation [21].

4 Regulation of biocides

4.1 United States

In the U.S., antimicrobial substances used in or on any FCM which may result in residues in or on food are either categorized as *food additives* or as *pesticide chemicals* [22]. The two terms are defined under § 321(q) and (s) of the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C., Chapter 9) [23]. Depending on their application, these substances are regulated by two different authorities (Table 2).

Table 2. U.S. Legislation for biocides

Regulated as	
<i>food additive</i> by FDA under § 348, FFDC A [23]	<i>pesticide chemical</i> by EPA under § 346a, FFDC A [23]
Antimicrobials used in or on food packaging , e.g.: <ul style="list-style-type: none"> • Surface sanitizing antimicrobial solutions. • Antimicrobials impregnated into the packaging (to protect either the packaging or the food). 	Food contact substances with an antimicrobial effect on permanent or semi-permanent food-contact surfaces (except food packaging), e.g.: <ul style="list-style-type: none"> • Surface sanitizing antimicrobial solutions. • Antimicrobials impregnated into the food contact surfaces such as counter tops, table tops, food processing equipment, cutlery, dishware or cookware.
Antimicrobial food contact substances (except food packaging) with no intended ongoing effect on any portion of the object. These chemicals are non-functional components of the final product, e.g.: <ul style="list-style-type: none"> • Antimicrobial substances used in the production of water-based adhesives or coatings. • Slimicides applied during paper production. 	
Material preservatives used to manufacture food contact articles (except food packaging). These antimicrobials are intended to preserve the final material or article, but do not have contact with the food itself, e.g.: <ul style="list-style-type: none"> • Polymeric resins for the manufacturing of food contact articles. • Coatings on conveyor belts. 	

Antimicrobials used in or on food packaging, material preservatives and non-functional antimicrobial components in food contact articles are regulated as food additives by the U.S. Food and Drug Administration (FDA) under FFDC A, § 348. Food contact substances with an antimicrobial effect in or on permanent or semi-permanent food-contact surfaces are regulated by the U.S. Environmental Protection Agency (EPA) under FFDC A, § 346a. A comprehensive list of food additives extracted from different parts of 21 CFR can be accessed on the FDA's homepage [24]. The regulatory and data requirements for pesticides including antimicrobials are regulated under 40 CFR Part 158 [25]. Maximum residue levels and exemptions of pesticide chemicals in food are listed under 40 CFR Part 180 [26]. More background information on the U.S. regulation of antimicrobials in food packaging can also be retrieved from a recent article by Misko [27].

4.2 European Union

Biocidal product regulation (BPR)

On September 1, 2013, the Biocidal Product Regulation (BPR, Regulation (EU) No 528/2012) came into effect in the EU [1]. It repeals the earlier Biocidal Products Directive (BPD, Directive 98/8/EC) [28]. The BPR aims at establishing a Union list of approved biocides (*active substances*) (Annex I of BPR). Companies have to submit a dossier subsequently evaluated by the European Chemicals Agency (ECHA). Based on an opinion prepared by ECHA, active substances may then either be approved, excluded or suggested for substitution by the European Commission. The approval of an active substance does not cover its nanoform. Active substances in nanoform need to be

assessed separately from the bulk material. *Biocidal products* contain approved active substances and require authorization during a second phase of the regulatory process. The biocidal products are grouped into 22 *product types* (PT), which are divided into four main groups (disinfectants PT 1-5, preservatives PT 6-13, pest control PT 14-20 and other biocidal products PT 21-22).

Treated articles have come in contact with or contain biocidal products or active substances and require labeling under certain conditions (e.g. when a claim of biocidal properties is made on the product or when the labeling of a specific active substance is legally required).

Types of biocides

In the context of FCMs, biocides are used for different purposes. They can be grouped into process biocides, surface biocides and food preservatives [29]. Depending on the application of the biocide, different regulatory actions are required.

- *Process biocides* are applied during manufacture of FCMs to prevent microbial contamination during production, storage or handling. These compounds are not intended to be carried over into the final product, but residues could still be present in the FCM. The manufacturer of FCMs has to adhere to article 3 of Regulation (EC) 1935/2004 guaranteeing that FCMs “do not transfer their constituents to food in quantities which could endanger human health” [30]. The setting of default limits for process biocides is currently being discussed (e.g. 10 ppb in the final product [29]). During the production of plastics, these chemicals are regarded as polymer production aids, which do not require authorization under Regulation (EU) No 10/2011. Under the BPR, process biocides need to be authorized for the use in different product types (PT 6: preservatives for products during storage; PT 7: film preservatives; PT 12: slimicides), but they will not be approved under PT 4 (food and feed are).
- *Surface biocides* added with the intent to exert an antimicrobial effect on the surface of plastic FCMs are authorized as additives and listed in Annex I of Commission Regulation (EU) No 10/2011 [31]. No such harmonized, positive lists exist for non-plastic FCMs. Non-plastic FCMs with intentionally added biocides nevertheless require additional approval as treated article under PT4 (food as feed area) of BPR.
- *Food preservatives* are biocides intended to be released from the packaging into the food or onto the food's surface. They are explicitly excluded from authorization under the BPR, but covered by Commission Regulation (EC) No 450/2009 on active and intelligent materials and articles [32]. Food preservatives need to be authorized under Regulations (EC) No 1333/2008 and (EC) No 1334/2008 [33].

Open questions regarding the responsible authorities

The different types of biocides in FCMs are regulated under different legal frameworks. Depending on the type of biocide, the risk assessment has to be carried out by ECHA or EFSA or by both agencies. No clear process has been defined so far on how to perform a combined risk assessment covering the provisions of Regulation (EC) No 1935/2004 [30] and BPR [1], but the European Commission published a discussion document in 2013 [29] and an amendment of the BPR was recently drafted [34]. The development of such a process will require further legal modifications of both above mentioned regulations.

Approved biocides

A total of 64 active substances are approved in accordance with the BPD and BPR [1, 28]. They do not contain any chemicals authorized for food and feed (PT 4), but only biocides applied in other product types. Currently, 57 active substances are still under review and may

be authorized for PT 4 [4]. They include organic acids, alcohols, halogenated compounds, aldehydes, amines, substituted phenolic substances, QATs, silver, and strong oxidizing substances such as silver dioxide, sodium hypochlorite and hydrogen peroxide.

Biocides in PT4

Several biocides that may be used in plastic FCMs in Europe are listed on a Provisional List [35]. They were assessed by EFSA, but only authorized in individual Member States, not at the Community level. These substances include triclosan and ten silver-based chemicals. Silver zeolite A and silver sodium hydrogen zirconium phosphate are currently also under the biocides review program for approval in PT 4. Applications for the other biocides of the Provisional List will have to be submitted by 1 September 2016; otherwise they cannot be placed on the market anymore.

5 Market data

Several comprehensive market studies on biocides were recently issued, but they are not publicly available [36-41]. The information summarized in this dossier was obtained from press releases and published digests of these market studies that refer to only limited data. Thus, it just gives a first impression of the figures, but for more detailed data, the original reports have to be purchased.

- In 2013, Biocide Information Limited estimated the global biocide consumption at nearly US \$5.4 billion for active substances and US \$12.4 billion at the formulated biocidal product level [41].
- In 2012, the European market size of specialty biocides was € 596 million corresponding to 112 000 tons production volume, whereas the U.S. market size summed up to US \$2 billion [39].
- For biocides, *Grand View Research, Ceresana and marketsandmarkets* forecast global revenues of US \$10.7 in 2020, almost US \$7.3 billion in 2019 and US \$9.6 billion in 2018, respectively [36, 37, 40].
- 5%, 4.6% and 4.32% Compound Annual Growth Rates (CAGR) were predicted for the periods 2014-2020, 2013-2018 and 2012-2016, respectively [37, 38, 40].
- Halogenated compounds covered more than 1/3 of the global biocides market in terms of volume and value in 2012 (Table 3) [37].
- Biocides are produced by the following chemical companies: Akzo Nobel N.V., Arkema S.A, Ashland Inc., BASF SE, Clariant International Ltd., DuPont (E.I.) De Nemours, Ercros, ISP, Kemira Oyj, Lanxess AG, Lonza Group Ltd., SK Chemicals Ltd., Solvay SA, The Dow Chemical Company, Thor Specialities, Troy Corporation and Ueno Fine Chemicals Industry, Ltd. [36-39]. In 2012, Ercros, Lonza and Dow Chemical were European market leaders in terms of volume [39].
- A Danish study from 2001 estimated that 13% of the total biocides consumption was used in the food and feed area disinfection, mainly by the food processing industry [42].

Table 3. Ranking of global market sizes of biocidal products in terms of value and volume [36, 37].

Rank	2011	2012	
	value	value	volume
1	Halogen compounds	Halogen compounds (>1/3)	Halogen compounds (>1/3)
2	Metallic biocides	Metallic biocides	Organic acids
3	Organosulfur compounds	Organic acids	Metallic biocides

6 Migration, exposure and contamination

In the case of active substances, the migration of biocides into the food may be intended for protecting food from contamination with microorganisms. In 2013, packaging that intentionally hinders microbial growth was reviewed by Larson and Klibanov. The authors differentiated between biocide releasing packaging and surface immobilized biocides. Highly specific active packaging solutions using e.g. ClO₂, antimicrobials and antifungals were illustrated in the paper. Migration of biocides may also occur non-intentionally resulting in the contamination of food. One example is the transfer of process biocides, e.g. isothiazolinones that are used in adhesives [43] or as slimicides in paper production [44]. In 2006, Coelhan and colleagues investigated 61 different beer cans from different countries and measured the biocide *ortho*-phenylphenol (OPP) in 40 of the samples [45]. The concentrations varied between 1.2 and 40 µg/L and it was assumed that OPP originated from the sealing of the cans. Further examples are conceivable, but our literature search did not reveal any systematic scientific study on the migration of biocides from food packaging.

As a consequence, exposure assessment is difficult. A comprehensive study about the exposure to biocides originating from products used for cleaning, washing, personal care, home improvement and pest control was published in 2010 [46]. Dermal exposure, inhalation and accidental oral exposure were considered as main exposure routes. The authors concluded that “exposure to biocides from household products may contribute to induction of sensitization in the population”. The study did not include any exposure to biocides originating from food. A comparable study focusing on this topic could fill current knowledge gaps.

7 Health hazards

7.1 Acute and chronic health effects

Many biocides used to disinfect surfaces are irritants and sensitizers and act on the skin, eyes and mucous membranes. They can lead to e.g. allergic contact dermatitis [47, 48] and asthma [49]. Especially occupational users of biocides might be at risk as a severe accident with chlorine gas in a poultry farm exemplarily demonstrated [50].

Kim and colleagues compiled a list of biocides used in Korean household products, many of which are also known to be used in or on FCMs, and performed a hazard classification [51]. Amongst the group of disinfectants, bleaches and germicides, eleven substances were reported to be carcinogenic and 51 products exhibited acute oral toxicity.

7.2 Resistance to biocides

One major problem occurring during the application of biocides is the development of resistant microbial strains after long-term exposure. This phenomenon was often observed when the concentration of biocide was not high enough to kill all cells (so-called sub-inhibitory concentration) [52]. Furthermore, bacteria that tend to form biofilms are often susceptible to biocides in their planktonic state, but not in the biofilm [53]. Both these problematic issues may also promote one another and result in unsatisfactory performance of the applied biocides. Bacteria and other microorganisms can either be intrinsically resistant or develop resistance mechanisms against biocides.

Intrinsic resistance

Intrinsic resistance mechanisms include efflux pumps that transport the biocide out of the cell and reduced membrane permeability caused by e.g. slime layers, thick outer membranes and complex cell walls.

Acquired resistances, co- and cross-resistances

Bacteria developing resistance against one specific biocide often acquire resistance to other biocidal agents at the same time [54]. This observation may be explained by two mechanisms. Both mechanisms are based on the transfer of genes between different bacterial strains: (i) Bacteria acquire a genetic element containing more than one resistance gene from another strain by horizontal gene transfer (co-resistance). (ii) Bacteria acquire only one resistance mechanism that is effective against several types of biocides (cross-resistance). These acquired resistances do not only concern different classes of biocides, but also co- and cross-resistances between biocides and antibiotics were observed frequently. This poses a significant risk to public health [55, 56].

In 2009, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) assessed antibiotic resistance effects of biocides [57]. The broad application of biocides at sub-inhibitory concentration was identified as one reason for the development of bacteria also resistant to antibiotics. Although several mechanisms of resistance apply to both biocides and antibiotics (e.g. efflux pumps, permeability changes, biofilms), the presence of biocides can also specifically induce the development of resistances against antibiotics. One reason is the generally elevated selective pressure for bacteria [58]. Thus, the transfer of mobile genetic elements between different bacterial species is one way to escape from this pressure. Often the genetic elements code for both the biocide and antibiotic resistance genes [59]. Cross-resistance mechanisms against antibiotics and biocides include changes in the envelope properties of the microbial cell and in the expression of efflux pumps [5].

Food production sites were identified by SCENIHR as one critical place promoting the development of bacteria resistant to both antibiotics and biocides [57]. The authors of the report suggest standardized assays combining repeated biocide exposures at sub-lethal concentrations with existing antibiotics susceptibility tests to fill knowledge gaps and prevent the development of further resistances. In a comprehensive review paper on the same topic, Gnanadhas and colleagues recommended highly specific biocide formulations and constant monitoring for resistant strains to reduce their development while maintaining or even improving the efficiency of both classes of antimicrobials [55].

8 Environmental impacts of biocides

Biocides strongly interact with living organisms and should be handled carefully. Nevertheless, they are also routinely released into the environment. For example chlorine, chlorinated compounds (e.g. triclosan) and metals were reported to be frequently detected in surface waters [60]. Not only the biocides themselves, but also their reaction products (e.g. dioxins and chloramines) are often highly toxic to aquatic organisms and might accumulate in body fat. The removal efficiency of other biocides such as parabens and *o*-phenylphenol in wastewater treatment plants was described to be more than 90% indicating a fairly efficient microbial degradation [61, 62]. Silver was reported to bind to sediments, suspended particles or activated sludge of sewage treatment plants, but the reactivity and toxicity of silver compounds is also influenced by the water quality [63].

Structurally simple, organic biocides (e.g. many alcohols, diethylamine and organic acids) are easily degraded by microorganisms once they are sufficiently diluted. On the other hand, biocides such as mercury, whose use in the production of FCMs has stopped decades ago, continue to pose a severe environmental problem in some regions [64].

Abbreviations

BPD	Biocidal Products Directive
BPR	Biocidal Products Regulation
CFR	Code of Federal Registration
CAGR	Compound Annual Growth Rates
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EPA	U.S. Environmental Protection Agency
FDA	U.S. Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
LDPE	Low-density poly ethylene
OPP	<i>ortho</i> -Phenylphenol
PT	Product type
QAT	Quarternary ammonium compound
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks

Glossary

Active substance refers to the chemical compound that carries the biocidal properties. Approved active substances are listed in Annex I of the BPR.

Antimicrobial substances are chemicals reducing the number of microorganisms. The term is often used in the U.S. legislation.

Biocidal products contain approved *active substances* and also require authorization before they can be placed on the EU market.

Biocides are chemicals used to suppress organisms that are harmful to human or animal health, or that cause damage to natural or manufactured materials (according to EU legislation).

Food additives include certain antimicrobial substances under U.S. law.

Food preservatives used in the context of FCMs are regulated as active and intelligent materials and articles in the EU.

Pesticide chemicals are defined as substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest under U.S. legislation.

Plant protection product is a specific term that is not included in the legal definition of the term *biocide* in the EU. It includes products used to protect plants from damaging influences, e.g. weeds, insects and diseases.

Process biocides are applied during manufacture of FCMs to prevent microbial contamination during production, storage or handling.

Product types are used to classify *biocidal products* in Annex V of the BPR.

Surface biocides are added with the intent to exert an antimicrobial effect on a material's surface.

Treated articles are articles treated with, or intentionally incorporating, one or more *biocidal products* containing *active substances* approved in the EU.

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