FEDERAL REGULATION OF BACTERICIDAL CHEMICALS USED IN BUILDING, INDUSTRIAL AND INSTITUTIONAL SANITATION PROGRAMS

L. S. STUART

Pesticides Regulation Division
Agricultural Research Service
United States Department of Agriculture

All bactericidal chemicals used in building maintenance programs and all germicides, disinfectants and sanitizers used in industrial and institutional sanitation programs except those recommended for application solely on or in the living body of man or other animals are subject to regulation under the Federal Insecticide, Fungicide and Rodenticide Act *(5)*. If a product is to comply with the requirements of this law it must be registered with the Department of Agriculture before shipment is made in interstate commerce, it must be offered for sale under claims and representations which do not differ in substance from claims and representations made in connection with its registration, packages must possess the net content claimed, the product must have the chemical composition claimed and give the results claimed when used as recommended and directed. The label must also bear a suitable product name and carry such caution and warning statements as may be necessary for the protection of the public.

The manufacturer and distributor will insist that the primary purpose of all labels and labeling is to promote the sale of the product. Frequently complaints are received to the effect that the requirements of the various labeling laws are such as to detract from the artistic appearance of the package and the sales appeal of the product. We would agree that a label artistically created in ignorance of these basic requirements may subsequently be seriously distorted by the addition of all the legally required information. If, on the other hand, the designer recognizes the necessity for these requirements provisions can be made for them so that the label will be both artistic and in compliance with the law. This has been demonstrated many, many times.

Label claims are second only to artistic appearance in promoting the sale of products. They are used as a primary basis for comparing competitive items and these must be given special attention by the Department in reviewing labels submitted for registration and examining official samples collected in connection with enforcement activities. This is important both from the standpoint of promoting fair trade practices and purchaser protection. Any program for evaluating label claims must be based on uniform definitions and a common understanding of words and terms *(6, 7)*. Therefore, we should review some of the words and terms which are commonly encountered in connection with the distribution of bactericidal chemicals.

The label claim "sterilizer," indicates that the product will destroy or eliminate all forms of life, applied as directed, which might ever be encountered in the applications recommended including all forms of vegetative bacteria, bacterial spores, fungi and viruses. The claim "sterilization" means the act or process of freeing from all living forms of life. These terms are quite often misused by laymen and scientists but there is no disagreement as to their technical meanings. The Department adheres to the strict technical definition and is supported in this position by the Council on Pharmacy and Chemistry of the American Medical Association *(1)* which has formally gone on record as disapproving of the use of the terms "sterile," "sterilize," and "sterilization" in any manner other than in their true meaning. They have stated in part "These terms are not relative and to permit their use in a relative sense not only is incorrect but opens the way to abuse and misunderstanding." Thus, such terms as "practically sterile," and "commercially sterile" are not considered acceptable. A product, an instrument, a surface is either sterile or it is not sterile. There is no intermediary state of sterility. The only chemicals that have been accepted for registration as sterilizers are ethylene oxide gas with application in especially constructed devices such as autoclaves and beta-propiolactone in the fumigation of tightly closed spaces.

The unqualified terms "kills germs" and "kills bacteria" are considered to be nearly synonymous to the term "sterilizer." Since no differentiation is made with respect to the type of germs which will be killed, the purchaser has a right to expect that the product will kill all germs and all bacteria including the most resistant bacterial endospores. These terms are badly misused in advertising media. The terms "kills most germs," "kills many germs," "kills most bacteria" and "kills many bacteria," are synonymous to the qualified terms "germicide," and "bactericide."

The term "germicide" refers to an agent that kills most germs. It is commonly considered applicable to substances that kill the growing forms but not necessarily the resistant spore forms of germs, except where the intended use is directed specifically against organisms forming spores, in which case, the spores must also be killed. The word is synonymous with the word "bactericide" except that the latter is a more precise term applying only to bacteria, whereas the word "germicide" may also be applied to substances active against microorganisms other than bacteria. The word "disinfect" means to free from infection, especially by destroying disease germs or other harmful microorganisms. Thus, a disinfectant is an agent that frees from infection. As with the word "germicide" it is commonly accepted as referring to products that kill the growing forms but not necessarily the resistant spore forms of bacteria except where the intended use is specifically against a spore forming infectious agent, in which case the spores would have to be killed. In a like manner, a disinfectant recommended for use specifically against an infectious virus would have to irreversibly inactivate the virus. The word implies a degree of specificity in that proper use is contingent on the purpose for which it is employed or the type of infectious agent which must be killed and/or for which there is reason to suspect may be present. A disinfectant is used where the complete elimination of an infectious agent is desired or required.

The word "sanitize" means to reduce the number of bacterial contaminants to safe levels as judged by public health requirements or to a significant degree where public health requirements have not been established or where the objective is not directly related to public health measures. The word "sanitizer" refers, therefore, to an agent which will sanitize. The words "sanitizing" and "sanitization" refer to processes which sanitize. They carry with them the connotation of cleanliness and are commonly used in reference to processes involving cleaning *(3, 8)*.

In a bacteriological sense to "disinfect" would be to "sanitize." However, due to the cleaning connotation referred to above it would probably not be acceptable to classify all disinfecting processes as sanitizing processes. To sanitize it might not be necessary to disinfect unless the object of the sanitizing process was the destruction of an infectious agent known or suspected of being present. The words "bacteriostatic," "fungistatic" and "germistatic" all refer to inhibition of growth with bacteria, fungi, and germs respectively as opposed to a cidal or killing effect. Since it has been shown that microorganisms in a state of chemical stasis can initiate infections in living animals, static treatments should not be recommended or used as replacements for cidal or disinfecting processes. It is apparent that this fact is not clearly understood by many sanitarians and for this reason the Department is now requiring label disclaimers on such products to the effect that they are not to be used in cleaning processes as a substitute for disinfectants. The word "antiseptic" has the broad dictionary definition of a substance opposing sepsis, putrefaction or decay. The Federal Food, Drug and Cosmetic Act *(4)* further defines this word as related to the labeling of drugs as a germicide, except in the case of a drug purporting to be or represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body. Most scientists believe that this word should be restricted to use with products recommended for applications on or in the living body of man or other animals, and that applications in describing or labeling other types of products are misleading. According to such a restriction, the legal definition given in the Federal Food, Drug and Cosmetic Act *(4)* would be the only acceptable definition.

The word "sporicide" refers to a substance that will kill bacterial spores. Sporicidal claims may be accepted in connection with the labeling of germicides if the manufacturer submits acceptable data to show that the product will be effective against bacterial endospores, names the spores it will kill, and includes in the labeling specific directions for obtaining such results as opposed to the directions for disinfecting against the vegetative forms of bacteria. A "germicidal-detergent" would through basic definition have to possess the properties of both a germicide and a cleaner. Likewise, a "detergent-sanitizer" would have to have the properties of both a cleaner and a sanitizer. These designations may not necessarily indicate that the product will give the dual results named in one and the same application, but this is clearly implied and if it is not the case it is considered to be the responsibility of the manufacturer to provide adequate and clearly understandable directions on his label for obtaining both results.

The word "household" in the phrase "kills household germs" is usually considered to be qualifying in that it refers to the ordinary germs found in homes rather than germs associated with specific disease outbreaks. A claim such as "kills 99 percent of all household germs" would not be valid even for a disinfectant properly applied unless 99 out of each 100 species of bacteria found in households were killed. A 99 percent reduction in the total bacterial population in the household as measured by dilution plate counts on samples taken from representative surfaces would not support such a claim, although it

might support a claim such as "reduces the total number of household bacteria by 99 percent."

The claim "germ-proof" has been introduced in sales promotion programs by distributors of antimicrobial chemicals. There appears to be wide differences of opinion in the trade and among consumers over the meaning of this term. The dictionary definition of the combining form of the adjective "proof" firmly denotes imperviousness to, ability to withstand, and resistance against. Thus, the word must be assigned the basic meaning of resistance against the action of germs. Since it is recognized that germs attack, deteriorate, and destroy inanimate materials, and substances, it must be acknowledged that any process that protects materials against attack by bacteria is a germ-proofing process. On the other hand, the term frequently has been used in labeling and advertising with other words in a manner which clearly implies activities greater than this, and it has been claimed that a germ conscious public interprets this term as assuring freedom from infectious bacteria. This may be true, but it would seem technically unsound to classify a germ-proof material as equivalent to a material possessing self-disinfecting properties unless labeling and advertising claims associated therewith were such as to show that this was the intent of the manufacturer or distributor. "Self-sterilizing," "self-disinfecting," "actively germicidal," and "self-sanitizing" claims for surfaces and treated materials are frequently claimed and implied. Claims of this type have led to a great deal of confusion among sanitarians and deserve special attention. The nature of bacteria is such as to virtually rule out the possibility of the production of self-sterilizing, self-disinfecting or actively germicidal materials or surfaces. Bacteriostatic and self-sanitizing materials and surfaces may be encountered as the result of treatments with bactericidal chemicals but it should be emphasized that the value of such residual activities in sanitation programs must be considered to be within the mitigating category and should not be classified as protective insofar as preventing the spread of infectious bacteria is concerned.

Obviously, such a claim as "permanently germicidal" for a treated surface could not be justified.

Claims for effectiveness against specific diseases and specific infectious bacteria and viruses are commonly proposed and/or encountered. It is considered to be improper to claim that applications of any germicide or disinfectant to inanimate surfaces in a sanitation program will be effective against any specific disease. A disease is a condition and the words "typhoid," "tuberculosis," "cholera," "poliomyelitis," "anthrax," etc., describe specific pathological conditions. When used in labeling and advertising they imply that the product may have value in the treatment of the specific condition or conditions named and this is seldom if ever true. On the other hand, claims for effectiveness against the specific causative agents of diseases are acceptable, if true. Such claims are in basic agreement with the specificity connotation in the definition of the word "disinfectant."

In reviewing claims of this type proposed in connection with applications for registration the Department takes the position that it is the responsibility of the applicant to submit acceptable experimental evidence to show that the claim is true before it can be accepted. The type of experimental evidence considered to be acceptable will vary depending upon th organism and the nature of the disease. For example, with *M. tuberculosis* the manufacturer is required to submit data developed by *in vivo challenge* procedures because of the wide variations known to exist between virulent and avirulent strains of this organism and the difficulties encountered in growing these bacteria in artificial culture media.

The Federal law clearly states that bactericidal chemicals are *misbranded* if the labeling does not contain directions for use which may be necessary and, if complied with, adequate for the protection of the public. This has been interpreted by the Department to mean that the purchaser will obtain the results promised if he follows the directions given, without injury to person or property. It would seem obvious from this requirement that as the number of claims and recommendations are increased on the label so will the requirements for use directions in the labeling be increased. The concentration and mode of application of a specific product necessary to give an effective germicidal rinse with a cleaned beer glass could not ordinarily be expected to give effective disinfection in the cleaning of a terrazzo tile floor in a public wash room, or effective disinfection in a spray application to equipment, floors and walls of a dairy barn.

Germicidal chemicals vary with respect to acceptability in different applications. While strongly acid germicidal detergents may give effective disinfection of porcelain fixtures in bathrooms it would be difficult if not impossible to give directions for their use in disinfecting marble floors which would comply with the provisions of the Act. In a like manner, a highly odoriferous cresylic acid preparation might give effective disinfection of dairy farm milking equipment if applied according to certain directions but it is doubtful that any directions for such an application could ever be accepted as meeting the provisions of the law because of such factors as toxic residues and the contribution of off flavors and odors to milk. Thus, in general it can be stated that the

requirements for use directions vary according to the recommendations made, and the nature of the product.

With applications of chlorine type germicides, quaternary ammonium formulations and the so-called iodophors certain basic patterns of application in disinfecting dishes and glasses in restaurants and taverns and in sanitizing dairy and food processing utensils have been clearly established as acceptable to public health officials, and these patterns are used as a guide in determining the adequacy of the use directions proposed for or employed in labeling under the Federal law. It cannot be claimed that the minimum requirements of the Federal law in all these cases will meet all of the various local ordinance requirements on application procedures for such products, for these vary considerably with respect to such details as equipment requirements, concentration, temperature and exposure time. Nevertheless, some degree of uniformity does exist and by weighing the relatively uniform requirements against test results obtained under conditions of use a reasonably effective regulatory program has been developed.

In the case of products recommended for use on floors, walls, and fixtures in buildings and institutions, disinfecting and sanitizing procedures have not been studied by bacteriologists and public health officials sufficiently to develop uniform patterns of acceptable public health application procedures according to the chemical types of formulas available. During the past three years the emergence of the staphylococcus disease problem in hospitals and local communities has intensified interest in premise disinfectants and it is expected that studies initiated in connection with this problem will produce data which should eventually clarify this situation.

Currently in those situations where no official public health or professional medical recommendations exist, the Department bases its requirements on tests conducted in its own laboratories and/or information submitted by manufacturers on individual products. Most of the bactericidal chemicals employed in building maintenance routines and in industrial and institutional sanitation programs fall within this category.

Studies to determine effectiveness used as directed with these products require a certain amount of *in situ* testing as well as *in vitro* laboratory evaluations. However, *in situ* testing is very time consuming in that procedures of this type which yield statistically significant data usually have to be quite extensive. Thus, the Department places special emphasis on the development of *in vitro* laboratory methods which give results that can be interpreted accurately in terms of recommended use concentrations in various types of applications. Such methods are much more applicable to routine regulatory testing operations than *in situ* procedures.

The method most commonly applied in the evaluation of premise germicides and disinfectants is the Association of Official Agricultural Chemists' Use-Dilution Method *(2)*. For example, it is held that with abrasive germicidal cleaners the decanted liquid from a slurry made with three parts of water and one part of product should kill the two test organisms named in this method. Results of tests by this procedure have correlated well *in situ* test results on such products. Likewise, it was found from *in situ* tests on toilet bowls that the concentration of porcelain cleaners which will kill in this method if vigorously appplied will give reasonably reliable disinfection of toilet bowl surfaces. In such evaluations a toilet bowl is considered to carry 96 ounces of residual water. Similarly, this method is employed to determine the maximum dilution of floor germicides which can be expected to be effective in disinfecting. *In situ* studies on floors have indicated that such products cannot be expected to disinfect at dilutions any higher than those effective in this method. They also indicated that the effective dilutions in this method might not provide for disinfection of floors if the product failed to provide a cleaning action in application or if an efficient precleaning job had not been done.

These latter results focused attention on combination germicidal-detergents. Such products have received wide acceptance for applications of this type and it is commonly recognized that their use avoids the serious problem of incompatibility between the specific germicidal chemical and residues of commercial cleaners inherent in two step applications. Unfortunately, an accurate method for determining the degree of cleaning necessary to get an acceptable result in disinfecting in either a one step or two step operation has not, as yet, been developed.

This brief review covers only certain aspects of the regulatory problem with the class of materials under consideration. However, the definitions and illustrations presented should provide an insight into some of the considerations involved in the Department's administration of the law.

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OBSERVATIONS ON THE EFFECTIVENESS OF BACTERICIDAL AGENTS IN RUBBER AND RUBBER-LIKE MATERIALS USED IN MILKING MACHINE INFLATIONS

J. C. WHITE

Department of Dairy and Food Science, Cornell University, Ithaca, New York

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The weakest link in the sanitary chain between the cow and the consumer has often been the milking machine. While it is easy to keep the metal parts of a milking machine clean with relatively simple cleaning procedures, it is often difficult to keep the elastic parts in excellent condition because of the mutual solubility of the elastomers with fat. Fat is only one of the deteriorating agents of the elastic parts. Depending upon the formulation of the inflation, it is more or less vulnerable to light, oxygen, ozone, abrasion and other chemical and physical agents.

Inflations and other elastic parts are subject to many kinds of deterioration. Time alone is an important factor, and the relatively slow distribution of parts from manufacturer through distributor and jobber to the farmer, uses up a lot of the potential life of an inflation. To be completely satisfactory, an inflation must have good milking characteristics. It must not be tacky, it must have good resilience. It should be resistant to swelling from water absorption or fat absorption, and it should resist set, the tendency to take on a new shape when held under stress.

The stress of constant flexing should not cause cracking of the inflation, and the surface should not craze like old varnish. Some of the surface characteristics may not be due to the compound and its deterioration but are due to the nature of the surface of the forming mold. If the mold is rough, so is the inflation.

But most serious of all the problems is cracking caused by contact with ozone. Inflations are attacked by ozone and the surface may be permanently destroyed. Ozone is produced by electric motors and is present in small but destructive amounts in the atmosphere of most milk houses.

Surface deterioration of inflations is important because these changes produce conditions which can harbor bacteria. Often the elastomer cannot be properly cleaned. As bacteria grow, they not only help to destroy the inflation but, more important, increased numbers of bacteria are shed into the milk passing through the inflation. High bacterial counts are a principal quality problem of dairy farmers and, in our opinion, deteriorated inflations are a principal cause. Inflations are most often discarded because they are suspected of contributing to the bacterial count.

Previous work done in this laboratory *(3)* has indicated the overall superiority of neoprene inflations over natural rubber. This superiority was shown not only in greatly increased useful life on the farm and in better milking, but also in generally lower bacterial populations because the inflations exhibited surfaces which were much less likely to harbor bacteria mechanically.

In a further effort to reduce the bacterial population of the inflations on milking machines, work was initiated to find suitable bactericidal or bacteriostatic agents which could be incorporated into the elastomer to help control bacteria without impairing the quality of the inflation.

English workers, Cousins *et al. (2)*, have reported a study made with inflations containing tetramethylthiuram disulphide. Their inflations have been found to be mechanically poor and only very limited success with reduced counts could be shown.

Recent advances in bactericidal and bacteriostatic agents led us to believe that it might be possible to