Environmental Protection Agency

determine the applicability of data requirements to specific uses. The Antimicrobial Pesticide Use Site Index, which will be updated periodically, is available from the Agency or may be obtained from the Agency's Web site at http://www.epa.gov/pesticides.

§ 158.2203 Definitions.

The following terms are defined for the purposes of this subpart:

Disinfectant means a substance, or mixture of substances, that destroys or irreversibly inactivates bacteria, fungi and viruses, but not necessarily bacterial spores, in the inanimate environment.

Fungicide means a substance, or mixture of substances, that destroys fungi (including yeasts) and fungal spores pathogenic to man or other animals in the inanimate environment.

Microbiological water purifier means any unit, water treatment product or system that removes, kills or inactivates all types of disease-causing microorganisms from the water, including bacteria, viruses and protozoan cysts, so as to render the treated water safe for drinking.

Sanitizer means a substance, or mixture of substances, that reduces the bacteria population in the inanimate environment by significant numbers, but does not destroy or eliminate all bacteria. Sanitizers meeting Public Health Ordinances are generally used on food contact surfaces and are termed sanitizing rinses.

Sterilant means a substance, or mixture of substances, that destroys or eliminates all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses

Tuberculocide means a substance, or mixture of substances, that destroys or irreversibly inactivates tubercle bacilli in the inanimate environment.

Virucide means a substance, or mixture of substances, that destroys or irreversibly inactivates viruses in the inanimate environment.

§ 158.2204 Public health and nonpublic health claims.

(a) Public health claim. An antimicrobial pesticide is considered to make a public health claim if the pesticide product bears a claim to control pest microorganisms that pose a threat to human health, and whose presence cannot readily be observed by the user, including but not limited to, microorganisms infectious to man in any area of the inanimate environment. A product makes a public health claim if one or more of the following apply:

- (1) A claim is made for control of specific microorganisms that are directly or indirectly infectious or pathogenic to man (or both man and animals). Examples of specific microorganisms include, but are not limited to: Mycobacterium tuberculosis, Pseudomonas aeruginosa, Escherichia coli (E. coli), human immunodeficiency virus (HIV), Streptococcus, and Staphylococcus aureus. Claims for control of microorganisms infectious or pathogenic only to animals (such as canine distemper virus or hog cholera virus) are not considered public health claims.
- (2) A claim is made for the pesticide product as a sterilant, disinfectant, virucide, sanitizer, or tuberculocide against microorganisms that are infectious or pathogenic to man.
- (3) A claim is made for the pesticide product as a fungicide against fungi infectious or pathogenic to man, or the product does not clearly state that it is intended for use only against nonpublic health fungi.
- (4) A claim is made for the pesticide product as a microbiological water purifier or microbial purification system.
- (5) A non-specific claim is made that the pesticide product will beneficially impact or affect public health at the site of use or in the environment in which it is applied, and:
- (i) The pesticide product contains one or more ingredients that, under the criteria in 40 CFR 153.125(a), is an active ingredient with respect to a public health microorganism and there is no other functional purpose for the ingredient in the product; or
- (ii) The pesticide product is similar in composition to a registered pesticide product that makes antimicrobial public health claims.
- (b) Nonpublic health claim. An antimicrobial pesticide is considered to make a nonpublic health claim if the