



# For Your Information

## Consumer Products Treated with Pesticides

### Background

In recent years, consumers have been increasingly concerned about the presence of bacteria in or on various items. In response to these fears, many consumer products that are treated with antimicrobial pesticides have appeared in the marketplace. These products bear implied or explicit public health pesticidal claims to protect the public against harmful microorganisms -- bacteria, fungi, and viruses. Some of these products include cutting boards, kitchen sponges, cat litter, toothbrushes, and juvenile toys.

Under the Federal law that regulates pesticides, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), companies cannot make public health pesticidal claims for any product distributed or sold unless the product has been approved and registered (licensed) by EPA, or is covered by an exemption from registration. If covered by an exemption, such a product may claim only that it contains a pesticidal preservative to protect the product itself.

These pesticides are known as materials preservatives.

Consumer and other products that incorporate materials preservative pesticides in order to preserve the product itself, or for other purposes, are called "treated articles." EPA has seen no evidence that these products prevent the spread of germs and bacteria in humans. Pesticide treated products that are not registered by EPA cannot make any public health claims, such as "fights germs," "provides antibacterial protection," or "controls fungus."

Nonetheless, these types of unauthorized public health pesticidal statements are being made. EPA is concerned about these statements because, in addition to being unlawful, they also are potentially harmful to the public -- if people believe that the product has a self-sanitizing quality, they may not practice standard hygiene to prevent the transmission of harmful germs. Consequently, the public's health may be less protected.

**EPA regulates pesticides that kill microbes such as bacteria, viruses, or algae on non-living surfaces. Antibacterial soaps, lotions, and other similar personal-care products are regulated by the Food and Drug Administration.**

For that reason, EPA advises consumers not to rely on antibacterial claims as a substitute for following common-sense hygienic practices. EPA does not know whether these treated products work as claimed.

As a result, EPA is seeking public comments on a recently issued draft guidance document that would describe the types of claims that can be made about pesticide treated products. Once final, the guidance will be intended to set forth EPA's policy with respect to the scope of the treated articles exemption [40 CFR 152.25 (a)]; provide examples of acceptable and unacceptable claims; and give examples of wording that would be acceptable for use on labels and advertisements for products that qualify for the treated articles exemption. This action will be intended to help consumers make more informed decisions about protecting their health, and to serve as the basis for preventing illegal, unsubstantiated, and potentially harmful public health claims from being made for unregistered consumer products treated with pesticides.

### **Current EPA Approach to Pesticide Treated Articles**

All products that make pesticidal claims must be registered by EPA before they may be legally marketed in the United States, unless they are exempt from registration. Under FIFRA, EPA created a limited exemption to allow pesticide treated articles to be sold without an EPA registration so long as product claims are limited to protection of the treated product itself. The treated articles exemption is set forth in 40 Code of Federal Regulations 152.25 (a).

**"Treated Articles" are consumer and other products that incorporate antimicrobial pesticides in order to preserve the product itself or for other purposes. Examples that fall within the treated articles exemption are paint treated with a registered pesticide to protect the paint coating from mold, and wood products, such as telephone poles, treated to protect the wood against insect or fungus infestation. In both cases the pesticide is registered for the intended use, and the sole purpose of treatment is to protect the article itself. Pesticides used in this manner are generally classified as preservatives and are widely used in the manufacture of textiles, plastics, paper, adhesives and coatings.**

An exempt product can not make implied or explicit public health claims (e.g., "kills germs," "stops E. coli ..."). Treated articles making public health claims must be registered with EPA. To obtain a registration, EPA requires specific efficacy data to support the product's public health labeling claims for the patterns of use, and other data to support the product's safety. Such products must meet other applicable registration requirements.

### **Proposed Guidance for Treated Articles**

The proposed guidance, once final, is intended to clarify the conditions under which the treated articles exemption will apply:

- ▶ Claims for treated articles or substances are limited to the following statement, "This product contains a preservative (e.g., fungicide or insecticide) built-in (or applied as a coating) only to protect the product."
- ▶ The treated articles exemption is available only for article protection and not for esthetic or public health uses.
- ▶ Treated kitchen accessories or other food contact articles such as a cutting board, high chair or conveyor belt that may come in contact with food must carry the following qualifying statement, "This product does not protect users or others against food-borne bacteria. Always clean and wash this product thoroughly before and after each use."
- ▶ Treated products that involve potential human contact with bodily fluids or excrement, e.g., blood, vomit, saliva, urine or feces, must carry the following qualifying statement, "This product does not protect users against bacteria, viruses or other disease organisms. Always clean and wash this product thoroughly before and after each use." Bed pans and potty seats are examples of these products.
- ▶ The preservative claim and qualifying statement on the product packaging (type, size, color) must be given no greater prominence than other described product features.

**Until the proposed guidance policy is final, the following language is an example of an acceptable non-public health claim for a product such as a sponge or cutting board:**

**"Antibacterial properties are built-in to inhibit the growth of bacteria that may affect this product. The antibacterial properties do not protect users or others against bacteria, viruses, germs, or other disease organisms. Always clean and wash this product thoroughly before and after each use."**

Compliance with the elements set forth in the PR Notice will be expected no later than 60 days following issuance of the final policy notice in order to give affected companies time to bring products into compliance. However, the Agency strongly encourages companies to conform their marketing of products to the proposed guidance notice as soon as they can.

### **Current Enforcement of the Treated Articles Exemption**

The treated articles exemption in 40 CFR Part 152.25 (a) was established in 1988. Since that time, enforcement actions have been taken against companies where the Agency deemed it necessary. The products involved in these actions were dealt with so as to resolve individual issues arising in each matter. As a result of the large variety of treated products and substances with diverse claims that have appeared in the marketplace, the Agency intends to replace this approach with comprehensive guidance to be set forth in a PR Notice. Until such guidance is in effect, the Agency will continue to use the current approach. Based on the enforcement cases to date, that approach includes the following elements:

- ▶ registered pesticides must be used to treat the treated article;
- ▶ no implied or explicit public health claims of any kind are made;
- ▶ the claims concerning the presence of a pesticide in the treated article are limited to protection of the treated article only; and
- ▶ when such claims involve antibacterial properties, a) the words "antibacterial," "antimicrobial," or "germicidal," or related terms, are not a part of the name of the product, and b) the permissible claims are qualified by statements indicating that the presence of the antibacterial properties does not protect users and others against disease and that users should follow prudent hygienic measures, i.e., cleaning and washing the article.

### **Enforcement Actions**

To address the growing trend of marketing unregistered pesticide treated products with illegal, unsubstantiated public health claims, EPA headquarters and Regional Offices have acted quickly and decisively to prohibit sales of these products by taking more than a dozen enforcement actions. EPA will continue to take action against companies that make illegal claims.

### **What Consumers Can Do**

While EPA has no basis for concern that the presence of these antimicrobial pesticides in consumer products could directly harm users, there are some common sense steps consumers can take to reduce the spread of germs, such as:

- ▶ wash hands frequently and thoroughly;
- ▶ wash surfaces that contact food with a detergent and water (e.g., utensils, cutting boards, counter tops); and
- ▶ wash children's hands and toys regularly.

### **For More Information**

Electronic copies of the Federal Register announcement and guidance notice are available from the EPA Home Page at the Federal Register - Environmental Documents entry under Laws and Regulations (<http://www.epa.gov/fedrgstr/>). To receive a fax copy of either document, call (202) 401-0527 and ask for item 6110. To obtain more information about the proposed guidance, contact Walter Francis, Environmental Protection Agency, (MC 7510W), 401 M St., SW., Washington, DC 20460, (703) 308-6419 (phone) or (703) 308-4687 (fax); email: [francis.walter@epamail.epa.gov](mailto:francis.walter@epamail.epa.gov).

EPA is accepting public comments on the proposed guidance notice until May 18, 1998. Submit written or electronic comments identified by the docket control number OPP 00530 by mail to:

**Public Information and Records Integrity Branch, Information, Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency  
401 M Street, SW, Washington, DC 20460. In person, bring comments directly to the OPP Docket Office, 1921 Jefferson Davis Highway, Room 119 of Crystal Mall #2, Arlington, VA. Comments may also be submitted electronically to: [oppdocket@epamail.epa.gov](mailto:oppdocket@epamail.epa.gov).**

