

Is Your Pillow a Pesticide? The EPA Steps Up Enforcement of Antimicrobial Advertising

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Introduction

Marketers and manufacturers beware. The products you advertise as “antibacterial” or “germ resistant” may be considered “pesticides” by the U.S. Environmental Protection Agency (EPA), and subject to registration and regulation. Samsung recently paid over \$200,000 in fines because the EPA declared that its computer keyboards, advertised as “inhibiting germs,” were “pesticides,” which had not been properly registered with the EPA.¹ Target paid over \$40,000 to settle allegations that it sold unregistered pillows, mattress pads, and toilet seats(!), which according to the EPA were “pesticides” because the advertising stated that these products could kill germs.² Under the Federal Insecticide, Fungicide, Rodenticide Act (FIFRA), products that claim to kill or repel bacteria or germs are considered pesticides, and must be registered with the EPA prior to distribution or sale. In addition, marketers must have substantiation for these types of “antimicrobial” claims to satisfy the registration process. Failure to do so, as a number of consumer marketers have learned, can result in substantial penalties.³

The EPA's enforcement of antimicrobial advertising claims has increased significantly in recent months. In May 2010, the EPA settled with four manufacturers, who paid a total of over \$500,000 to

resolve cases involving unsubstantiated antimicrobial claims. Califone International, Inc., which claimed that its headphones prevented “the spread of bacteria, mold, and mildew for student protection,” was assessed a \$220,000 fine.⁴ The maker of North Face shoes also paid over \$200,000 for making allegedly unsubstantiated “antimicrobial protection” claims.⁵ EPA targets have included a host of other products that would hardly be considered “pesticides” by most manufacturers, or by the consuming public: faucets, spigots, handles, light switches, garden hoses, and even a computer mouse.⁶

As Katherine Taylor, Associate Director of the Communities and Ecosystems Division in the EPA's Pacific Southwest Region notes, there are “more and more consumer products making a wide variety of antimicrobial claims” and “EPA takes these unsubstantiated public health claims very seriously.”⁷ Because the “EPA will take decisive action against companies making unverified public health claims,” companies should be aware of the registration process and the substantiation requirements under FIFRA.⁸

History of the Federal Insecticide, Fungicide, Rodenticide Act⁹

The regulation of pesticides is not new. The federal government first started regulating pesticides with the passage of the Federal Insecticide Act of 1910.¹⁰ Congress intended to reduce economic exploitation of farmers by outlawing the manufacturing and distribution of misbranded or adulterated pesticides. In 1947, Congress addressed the potential risks to human health posed by pesticides by passing the Federal Insecticide, Fungicide, Rodenticide Act.¹¹ FIFRA broadened the federal government's control of pesticides by requiring product label registration of all pesticides prior to their introduction in interstate commerce. Moreover, Congress placed the burden of documenting a pesticide product's efficacy and safety on the manufacturer. The 1964 amendments to FIFRA authorized the Secretary of Agriculture to refuse registration to pesticides that

were deemed unsafe or ineffective and to order their removal from the market.¹² At this point, however, the reach of FIFRA extended only to traditional “pesticides,” such as those used for agricultural purposes.

After the establishment of the EPA in 1970, Congress transferred the administration of FIFRA from the USDA’s Insecticide Board to the newly created EPA by passing the Federal Environmental Pesticide Control Act (FEPCA) in 1972.¹³ FEPCA, largely still in place, significantly transformed FIFRA and turned it from a labeling statute into a comprehensive scheme for regulating the distribution, sale, and use of pesticide products.

Among these changes, FEPCA specified methods and standards of control for the registration process in greater detail, required all persons who apply pesticides to follow all label directions, classified pesticides for restricted use or general use, and obligated states to adopt parallel laws.¹⁴ Moreover, the statute authorized the EPA, as the Administrator, to take enforcement actions against manufacturers and retailers claiming that their products contain antimicrobial properties or making other public health claims, without first registering the product as a pesticide and submitting the required efficacy data to the agency. Subsequent amendments have further clarified the statute, as well as the duties and responsibilities of the EPA.¹⁵ The most recent amendments to FIFRA occurred in 1996 with the Food Quality Protection Act.¹⁶

How FIFRA Works

Generally, FIFRA is a regulatory statute which requires registration of pesticide products and pesticide-production facilities, as well as proper pesticide labeling. Under FIFRA, no one may sell, distribute, or use a pesticide unless it is registered by the EPA, or it meets a specific exemption as described in the regulations. FIFRA defines a pesticide as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.”¹⁷ Further, a “pest” is defined

as “(1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals). . .”¹⁸ In other words, products are subject to FIFRA if they contain claims that they are antibacterial or germicidal (“germ-resistant”). An “antimicrobial pesticide” is defined as one that “is intended to (i) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or (ii) protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime”; and that is not subject to a food additive regulation or a pesticide tolerance under the Federal Food, Drug, and Cosmetic Act.¹⁹ Thus, products making antimicrobial claims are generally subject to FIFRA requirements.²⁰

Registration and Labeling of Products

All pesticides, including antimicrobials, must be registered with the EPA and must have the appropriate scientific data, including testing results, necessary for their registration. Generally, there are six types of pesticide registrations: unconditional registrations, conditional registrations, supplemental registrations, state special local needs registrations, restricted use pesticides, and emergency exemptions from registration.²¹ The type of registration granted is dependent on the toxicity and behavior of the product in the environment.²² Manufacturers are required to conduct studies and compile data about the product, including the product’s chemistry and hazards to humans.²³ The type of data and/or studies required depends on the type of registration being requested. The information submitted by the manufacturer is reviewed, along with information compiled by the EPA and the EPA decides whether to register the product, whether the pesticide would present an unreasonable risk to human health or the environment, and what type of registration, if any, will be granted to the pesticide.²⁴

Registration also includes the EPA's approval of the pesticide product's labeling, including advertising claims incorporated in the label.²⁵ The Agency reviews a pesticide product's labeling and informs applicants or registrants if the Agency finds specific statements, claims, product brand names, logos, pictures, or other aspects of the labeling to be potentially false or "misbranded."²⁶ Such statements cannot be used. Examples of misbranding include:

- A false or misleading statement concerning the composition of the product;
- A false or misleading statement concerning the effectiveness of the product as a pesticide or device;
- A false or misleading statement about the value of the product for purposes other than as a pesticide or device;
- A false or misleading comparison with other pesticides or devices;
- Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless," or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and
- Non-numerical and/or comparative statements on the safety of the product, including but not limited to: "Contains all natural ingredients" and "among the least toxic chemicals known."²⁷

There are also exemptions from FIFRA.²⁸ An article or substance, treated with or containing a pesticide, is exempt from FIFRA if: (1) the incorporated pesticide is registered for use in or on the article or substances, and; (2) the sole purpose of the treatment is to protect the article or substance itself.²⁹ An example of such an exemption would be treated wood—the wood is treated to protect against insect or fungus infestation.³⁰ Other examples include treated articles where pesticides are

incorporated because of their ability to inhibit the growth of microorganisms which may cause odors or to inhibit the growth of mold and mildew.

Penalties

There are a number of ways that the EPA can penalize a manufacturer or distributor making unregistered or unsubstantiated pesticide claims. Once the EPA determines that a FIFRA violation has occurred, it chooses an appropriate level of enforcement response for the violation. In determining the level of action, the EPA generally considers the severity of the FIFRA violation, the company's compliance history, and the relevant facts and circumstances of each case.³¹

A civil penalty is the "preferred enforcement remedy for most violations."³² The EPA is authorized to assess manufacturers and distributors of pesticides a penalty of up to \$7,500 for each violation of FIFRA.³³ In determining the amount of the civil penalty, the EPA is required to consider the size of the business, the effect of the penalty on the person's ability to continue in business, the economic benefit of non-compliance, and the gravity of the violation.³⁴ The statute also provides a civil penalty matrix to assist the Agency in computation of the final fine.³⁵

Where the EPA has reason to believe on the basis of inspection or tests that a pesticide is in violation of any provision of FIFRA, it has authority to issue a Stop Sale, Use or Removal Order (SSURO).³⁶ A SSURO is generally issued against persons who own, control, or have custody of pesticides where pesticides have "labeling that is materially misleading or fraudulent and, if followed by a user, is likely to cause a significant health hazard or serious adverse environmental effect."³⁷ Specifically, a SSURO could be issued for labeling on products that are ineffective for the purposes claimed or that bear false or misleading safety claims. No court order or seizure of the alleged illegal products is necessary to obtain a SSURO.³⁸ The EPA merely has to confirm that a violation has

occurred and it can seek civil penalties and a SSURO.³⁹

Other options available to the EPA include seizures and injunctive relief.⁴⁰ Both procedures require the EPA to initiate action in United States District Court.⁴¹ The EPA will initiate a seizure action in certain circumstances, including where the EPA has issued a SSURO but the company has not complied with it, or where the EPA has reason to believe that if it issued a SSURO, the company would not comply with it.⁴² The EPA may opt to seek injunctive relief where there is a violation of a SSURO and a civil penalty could not provide an appropriate or timely remedy to deter further violations, or where there is continued distribution of an unregistered pesticide after the Agency has taken action against it.⁴³

Recent Enforcement Actions

The EPA's enforcement actions have involved traditional pesticides, such as sanitizers and disinfectants, but, as noted above, they have also included products not traditionally considered pesticides such as toilet seats, shoes, and pillows. Recent enforcement actions and settlements for products not traditionally considered pesticides include:

Shoes (VF Outdoor, Inc (The North Face)). In May 2010, the manufacturer of North Face shoes, VF Outdoor, Inc., paid \$207,500 for allegedly making unsubstantiated claims about the "antimicrobial protection" in its shoes.⁴⁴

Computer Keyboards (Samsung). In October 2009, the EPA assessed a \$205,000 fine against Samsung for violating FIFRA by publicizing that Samsung keyboards were antimicrobial and inhibited germs and bacteria. As explained above, Samsung's public health claims in promotional material about the keyboards on its netbook and notebook computer laptops rendered the products pesticides. In addition to paying the fine, Samsung agreed to stop making the "pesticidal claims" and

provide a certification that it complied with FIFRA by removing such claims. Additionally, Samsung agreed to notify its retailers and distributors to remove the pesticidal claims from labels, promotional brochures, and Internet content relating to the keyboards.⁴⁵

Computer Accessories (IOGEAR). On March 5, 2008, the EPA assessed a \$208,000 fine against ATEN Technology, Inc., acting for its subsidiary IOGEAR, for violating FIFRA by selling unregistered pesticides and making unproven claims about the antimicrobial effectiveness of three of its computer peripheral products: (1) a wireless laser mouse with nano-shield coating, (2) a laser travel mouse with nano-coating technology, and (3) a wireless keyboard and mouse combination. Specifically, the company made unsubstantiated public health claims about the products' abilities to control germs and pathogens, thereby rendering them pesticides under FIFRA.⁴⁶

Toilet Seats, Mattresses, and Pillows (Target). In September 2007, the EPA settled an enforcement action against Target, which included a \$40,950 penalty, for selling and distributing unregistered pesticides, in this case, antimicrobial toilet seats, mattresses, and pillows. All three products made "germ-killing" claims. As part of the settlement, Target agreed to remove the pesticide claims from the products.⁴⁷

Garden Hoses (Kmart). In October 2004, the EPA fined Kmart Corporation \$110,000 for selling a variety of garden hoses that claimed to inhibit mold, fungus, and bacteria growth because they were determined to be unregistered pesticide products.⁴⁸

Recent enforcement actions involving more traditional pesticides include:

Hospital Disinfectants (Lonza, Inc.). In July 2009, the EPA settled a pesticide enforcement action against Lonza, Inc., the nation's largest manufacturer of hospital disinfectants, for multiple FIFRA violations. The Agency alleged that Lonza

made misleading claims regarding the efficacy of two of its products: (1) Saniphor No. 450, registered with the EPA as a tuberculocide, but deemed ineffective against tuberculosis, and (2) 7 Healthcare Disinfectant Neutral Cleaner, which did not effectively kill the pathogen *Pseudomonas aeruginosa*, despite the claim as such on its label. As a result of the investigation, Lonza agreed to pay more than \$550,000 in fines. Under a previous settlement in 2008, Lonza also developed an unprecedented nationwide quality-assurance program to ensure that the efficacy of disinfectant products it sells to hospitals are satisfactory.⁴⁹

Fly Repellants (Eqyss International, Inc.). In September 2008, the EPA fined a horse products company, Eqyss International, Inc., \$72,000 for distributing four unregistered pesticides including products that repel flies from horses, products intended to kill germs and bacteria on bedding for horses, and a product intended to prevent unwanted chewing by horses.⁵⁰

Toilet Bowl Cleaners and Household Cleaners (Safeway, Inc.). In July 2007, the EPA fined Safeway, Inc. \$675,000 for selling unregistered household cleaning products because the product labels claimed the products could disinfect and remove mold and mildew. The products included Safeway Heavy Duty Toilet Bowl Cleaner and Safeway Liquid Cleanser with Bleach.⁵¹

What's Next for FIFRA and the EPA

With the spread of environmental marketing and public-health marketing claims, the EPA has identified two areas of concern related to FIFRA enforcement. The first area deals with brand or company names that are false or misleading. The second deals with products that make misleading public health claims, such as antimicrobial claims.

Recently, the EPA revived draft guidance originally issued in 2002 addressing products with brand names that, in a false or misleading manner, state or imply safety, efficacy, or comparative claims, or are

otherwise false or misleading.⁵² The 2002 guidance was never finalized and the EPA, in May 2010, reissued revised draft guidance for public review and comment on the same subject.⁵³ Public comments on the draft guidance were originally due on June 18, 2010, but the EPA extended the comment period to August 17, 2010.⁵⁴

The purpose of the guidance is to assist manufacturers and distributors in better understanding the circumstances under which product brand names are potentially false or misleading and what kinds of corrective actions are necessary for registered products already bearing such brand or company names.⁵⁵ The draft guidance clarified that a pesticide product brand name or company name either by itself or containing or located in close proximity to a company name or trademark should not be false or misleading. Examples of such brand names include those that have the following words or phrases in the brand name or in close proximity to the brand name: "100% Pure," "Germ-Shield," "100% Protection," "All-Kill," "Safe," "Safer," "Safest," "Natural," "Non-Toxic," "Environmentally Safe."⁵⁶

To help registrants determine whether their brand or company names, alone or in context, are permissible, registrants should:⁵⁷

- Review the list of words and phrases provided by the draft guidance (some of which are discussed above) against the brand names of its products in light of the regulations and guidance and take corrective action, if warranted.
- Review the product brand name and labeling for false or misleading statements that have the potential to directly or indirectly mislead consumers, particularly those that suggest or declare that a product is safer or more effective than another product, even if both products meet the same standards for registration.

- Prepare and maintain the appropriate scientific research or other documentation information necessary to support the claims being made, as required by the EPA.⁵⁸

Although the draft guidance has not yet taken effect, manufacturers should consider taking corrective action to prevent a future compliance problem. Corrective action can include changing or deleting words, phrases, or company names in the product brand name or using disclaimers or qualifiers.⁵⁹ Once the guidance takes effect, the Agency will decide on a case-by-case basis whether a company or product name is permissible. Factors that the Agency will consider include: (a) the type of claim; (b) the severity of the false or misleading claims; (c) the degree to which the proposed qualifier/disclaimer language appears to mitigate the false or misleading nature of the words or phrases; (d) the similarity of the product brand name to other known false or misleading words or phrases; (e) the history of the product brand name, company name, or trademark; and (f) any supporting information supplied by the applicant, registrant, and distributors, such as a consumer survey.⁶⁰

The other major concern of the EPA deals with false or misleading advertising and labeling of antimicrobial pesticides.⁶¹ As discussed above, there are exemptions to the FIFRA requirements for certain treated articles and substances, but those exemptions only cover treated articles and substances bearing claims to protect the article or substance itself (i.e., treated wood). The exemption does not include articles or substances bearing implied or explicit public health claims against human pathogens.⁶² Such claims have dramatically increased in recent years, as evidenced by the penalties rendered against non-traditional pesticide products discussed above, such as pillows and garden hoses. Where the claims for such products imply that the antibacterial or antimicrobial protection extends beyond the product itself and provides some benefit to a person's health, they are not exempt from FIFRA requirements and the label

and/or advertising violates the Act unless the label or claim is specifically registered as such.

The guidance provided by EPA offers some examples of public health claims.⁶³ They include:

- Claims for the control of specific microorganisms or classes of microorganisms that are directly or indirectly infections or pathogenic to humans (including E.coli, streptococcus, and staphylococcus aureus).
- A claim of "antibacterial," "bacterial," or "germicidal" activity or references in any context to activity against germs or human pathogenic organisms implying public health-related protection is made.
- A claim to control the spread of allergens through the inhibition or removal of microorganisms such as mold or mildew.
- A non-specific claim that the product will beneficially impact or affect public health by pesticidal means at the site of use or in the environment in which applied.⁶⁴

Where an article or substance makes a public health claim, such as those above, that implies efficacy beyond the product and to a person, the article is not exempt and must be registered.

In addition to providing examples claims that the EPA considers public health claims, the EPA guidance also provided a list of claims where there is no exemption and the manufacturer or distributor must register the product as a pesticide and meet all the requirements of FIFRA. The list includes the following terms and phrases: antibacterial, bactericidal, germicidal, "kills pathogenic bacteria," "effective against E.Coli and Staphylococcus," "reduces risk of food-borne illness from bacteria," "provides germ resistant surface," "reduces risk of cross-contamination from bacteria," "controls allergy causing microorganisms," "improves indoor

air quality through the reduction of microorganisms.”⁶⁵

There are certain claims, however, which the EPA is likely to consider acceptable for use with treated articles or substances.⁶⁶ Most noteworthy for manufacturers are claims involving odor resistance.⁶⁷ This includes claims such as “resists odors—this product has been treated to resist bacterial odors,” “inhibits the growth of bacterial odors,” “odor-resistant.”⁶⁸

Manufacturers and distributors should review their product labels and the marketing associated with such products to ensure that they are not making public health claims without the proper registration. When in doubt, companies are encouraged to request a written opinion on the labeling and marketing of the product from the EPA.⁶⁹

Conclusion

Even the most unexpected products, like computer keyboards and toilet seats, can be deemed pesticides if their labels or advertising tout their antimicrobial benefits. As the EPA increases its enforcement of FIFRA violations, companies that manufacture or distribute products that claim to be “germ resistant,” “antibacterial,” or otherwise antimicrobial must be aware of FIFRA and comply with its registration and substantiation requirements where necessary. The EPA merely needs to run a simple Internet search to find examples of FIFRA violations and to begin investigating a product. The fines for violations can be substantial and can be avoided by registering a product or discontinuing claims requiring registration. An understanding that FIFRA requirements may now apply to products such as pillows and mattress pads should prevent manufacturers from losing sleep over the EPA’s enforcement positions.

¹ Press Release, U.S. Environmental Protection Agency (“EPA”), Claims About Keyboards Result in \$205,000 Penalty for Samsung; Company Agrees to Stop Making Claims (Oct. 21, 2009), <http://yosemite.epa.gov/opa/admpress.nsf/ab2d81eb088f4a7e85257359003f5339/201d62b730b8262985257656005af84c!OpenDocument>.

² Press Release, EPA, EPA Settles with Target on Pesticide Violations (Sept. 8, 2007),

<http://yosemite.epa.gov/opa/admpress.nsf/eebfaebc1afd883d85257355005afd19/6d2a918df6f84d8f85257364005288cb!OpenDocument>.

³ See generally 40 C.F.R. Pt. 152. In addition to the EPA’s authority to regulate such statements, pesticide products are subject to the same broad requirements as all products, including the Federal Trade Commission’s Guidelines on Environmental Claims, 16 C.F.R. Pt. 260, and the FTC’s general authority under Section 5 of the Federal Trade Commission Act, to act against false or misleading claims.

⁴ Press Release, EPA, “The North Face” Parent Company, “Saniguard” Marketers, and Califone Fined More Than \$500,000 Over Antimicrobial Claims (May 6, 2010), <http://yosemite.epa.gov/opa/admpress.nsf/0/AC0C1AF1625888608525771B00561E83>.

⁵ Id.

⁶ Id. “Recent Enforcement Actions,” at *infra*, page 9.

⁷ Id.

⁸ Id.

⁹ See generally EPA, FIFRA Statute, Regulations and Enforcement (May 18, 2010),

www.epa.gov/compliance/civil/fifra/fifraenfstareq.html.

¹⁰ Pub. L. No. 61-152, 36 Stat. 331 (1910).

¹¹ Pub. L. No. 80-104, 61 Stat. 163 (1947).

¹² Pub. L. No. 88-305, 78 Stat. 190 (1964).

¹³ Pub. L. No. 92-516, 86 Stat. 973 (1972).

¹⁴ Id.

¹⁵ Pub. L. No. 94-140, 89 Stat. 751 (1975); Pub. L. No. 95-396, 92 Stat. 819 (1978); Pub. L. No. 100-532, 102 Stat. 2654 (1988); Pub. L. No. 101-624, §§ 1491-1499, 104 Stat. 3359, 3627-32 (1990); Pub. L. No. 102-237, § 1006, 105 Stat. 1818, 1894-97 (1991).

¹⁶ Pub. L. No. 104-170, 110 Stat. 1489 (1996).

¹⁷ 7 U.S.C. § 136(u) (1996); 40 C.F.R. § 152.15.

¹⁸ 7 U.S.C. § 136(t).

¹⁹ 7 U.S.C. § 136(mm)(1) (citing 21 U.S.C. §§ 346a, 348).

²⁰ See generally 40 C.F.R. § 152.10; § 152.8(a).

²¹ 7 U.S.C. § 136a(c)(5); 7 U.S.C. § 136a(c)(7); 7 U.S.C. § 136a(b)(1); 7 U.S.C. § 136c; 7 U.S.C. § 136p.

²² Id.

²³ 40 C.F.R. Pt. 158.

²⁴ 7 U.S.C. § 136a(c)-(d).

²⁵ 7 U.S.C. § 136a(c)(1)(C), (F).

²⁶ 7 U.S.C. § 136(q)(1); 40 C.F.R. § 156.10(a)(5)(ii).

²⁷ 40 C.F.R. § 156.10(a)(5).

²⁸ 40 C.F.R. § 152.25(a)

²⁹ Id.

³⁰ Id.

³¹ See EPA, FIFRA Enforcement Response Policy (Dec. 2009), www.epa.gov/compliance/resources/policies/civil/fifra/fifra-erp1209.pdf.

³² Id. at 10. Civil penalties are generally used where the FIFRA violation presents an actual or potential risk of harms to humans or the environment, or would impede the EPA’s ability to fulfill the goals of the statute, and the violation was apparently committed as a result of ordinary negligence, inadvertence, or mistake. Id.

³³ See 7 U.S.C. § 136l; FIFRA Enforcement Response Policy, *supra* note 31, at 10.

³⁴ See 7 U.S.C. § 136l; FIFRA Enforcement Response Policy, *supra* note 31, at 15-16. Note that the EPA revised its FIFRA Response Policy in December 2009 and has not given notice of any additional revisions in the wake of other agency enforcement policy revisions,