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When Is a Shower Curtain a Pesticide?: EPA Finally Clarifies Requirements for Germ-Fighting Products

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In recent years, consumers have seen a proliferation of products designed to help fight germs around the house. Some products are distributed with claims that the product can kill or control dangerous bacteria and other organisms that could grow on the surface of the product. Still others bear claims that state (or imply) that the product is effective at eliminating or controlling such organisms on the surfaces with which they come in contact. Products currently sold with ''antibacterial'' claims include soaps and cleaners, toothbrushes, toys, cutting boards, sponges, mops, shower curtains, cat litter, vacuum cleaner bags, pillows, and mattresses. Applying regulations that have just been clarified by the U.S. Environmental Protection Agency (EPA), some of these products must be registered as pesticides by EPA or their distributors could face fines or other punishment.

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In a previous article, this author analyzed how certain ''antibacterial'' products are regulated pursuant to the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and noted an upsurge in EPA enforcement actions against companies that made what EPA considered to be ''public health'' claims for such products.[1] In April of 1998, EPA issued for public comment a draft guidance document called a ''Pesticide Registration Notice'' (PR Notice) to clarify when a specific category of products that contain ''antibacterial'' ingredients (specifically ''treated articles'') are exempt from FIFRA's costly and time consuming registration process. EPA recently released its final guidance document after much deliberation and soul searching at the Agency. This article provides an overview of the relevant requirements in FIFRA and EPA's implementing regulations applicable to products that are treated with pesticides to preserve the product, summarizes EPA's final PR Notice, and discusses its implications for manufacturers and distributors.

EPA's Many Enforcement Actions

In recent years, EPA has taken dramatic and well publicized enforcement actions against persons who distribute consumer products that are treated with antibacterial pesticides and are marketed with antibacterial claims. A notorious example occurred in 1998 when EPA sent inspectors to a household products trade show in Chicago to search for unregistered products making what EPA considers to be ''public health'' claims. Based upon their findings, EPA inspectors is-

[1] Lawrence E. Culleen, *The War on Germs (and Germ-Fighting Products) Heats Up*, Chem. Reg. Rep. (BNA), Nov. 21, 1997, at 962.

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sued more than 15 ''stop-sale orders'' concerning the offending products.[2]

EPA publications tout its aggressive stance against distributors of such products. In its annual review of the Agency's enforcement program, EPA stated that compliance with antimicrobial product registration requirements is a specific priority for EPA's pesticide enforcement program.[3] EPA enforcement efforts include monitoring unregistered and ineffective antimicrobial products, as well as products that make false or misleading public health claims. In that publication, EPA singled out the following enforcement actions:

- EPA issued a stop sale order to Lifetime Hoan and fined it $66,000 for selling unregistered kitchen gadgets making alleged claims of antibacterial protection.
- EPA issued a stop sale order to Snow River Wood Products and fined it $26,400 for selling an unregistered cutting board allegedly claiming to fight salmonella and *E. coli*.
- EPA fined McNeil-PPC $100,000 for selling unregistered toothbrushes allegedly making antibacterial claims.[4]
- EPA entered into a consent order with Safetec of America, Inc. that required the company to pay a $100,500 civil penalty. EPA alleged that Safetec violated FIFRA by selling certain unregistered pesticide products. The company made claims on product labels and in catalogs concerning antimicrobial and disinfectant properties for these products, which included surface wipes, towelettes, and spill control products (encapsulators) that are used to clean up human bodily fluids in health care facilities.

Other recent EPA enforcement actions taken against distributors of unregistered products that have been treated with antibacterials included the following:

- In March 1999, an EPA administrative law judge found Micro Pen of U.S.A., Inc. liable for selling a product called Cleen Ball Pen because it was not registered as a pesticide.[5] The pens were stamped with the word ''Antibacterial Pen'' and the packaging and product literature made antibacterial claims. In November 1999, Micro Pen and EPA reached a settlement under which the company will pay a $35,000 penalty and stop marketing the product as antibacterial.[6]
- In October 1999, EPA entered into a settlement with the Hunter Fan Company. EPA charged the Memphis, Tennessee company with making unqualified antimicrobial claims for a humidifier. The settlement requires the company to pay a $105,600 penalty and make changes to the labels and packaging of humidifier and air purifier products.[7]
- In October 1999, a Rhode Island medical products manufacturer settled an EPA action alleging that the company sold medical storage bags that claimed to kill or control infectious micro-organisms on syringes stored in the bags. The bags were marketed as the ''Germbuster.'' The company, Welcon/Accorde Medical Products, will pay an $80,200 penalty.[8]
- In November 1999, EPA charged a New Jersey-based paint manufacturer called William Zinsser & Company with selling paint marketed as ''mildew-proof'' without obtaining a pesticide registration.[9]

Regulatory Background

FIFRA

FIFRA[10] regulates the distribution and sale of ''pesticide'' products. FIFRA not only applies to products that users commonly think of as pesticides, such as bug sprays and crop protection products, but it also applies to *any* non-exempt product intended for ''preventing, destroying, repelling, or mitigating any pest.''[11] For purposes of FIFRA, the term ''pests'' can include viruses, bacteria, and other microorganisms (e.g., HIV, salmonella, *E. coli*, TB) on surfaces such as home counter tops and in bathrooms. Thus, if a company markets a product claiming that it will either ''kill'' or simply inhibit the growth of ''germs'' on inanimate surfaces, that company is distributing a ''pesticide.''

In 1996, FIFRA was amended by the Food Quality Protection Act (FQPA).[12] As a result, FIFRA now defines and regulates ''antimicrobial pesticides''[13] as a special class of pesticides if they control the growth of microbiological organisms or protect inanimate objects, industrial processes, water, or other chemical substances from bacteria, viruses, fungi, protozoa, algae, or slime.

Product registration. In general, all pesticides, including antimicrobial pesticides, must be registered with EPA before they are distributed in the United States.[14] Failure to register a pesticide can subject the distributor to civil or criminal penalties.[15] However, the FIFRA registration process can be time consuming and expensive. To obtain a product registration, the registrant (typically the manufacturer) must submit to EPA administrative forms, proposed labels, information on the product's formulation, and health and safety data in support of the registration.[16] EPA conducts an exhaustive review of the data and to register the product the Agency must determine that the product, when used in accordance with its proposed label, ''will not generally cause unreasonable adverse effects on the environment.''[17]

Public health claims. EPA imposes additional requirements upon companies that make claims that use of their products may affect the public health. For example, unlike other pesticide products, EPA reviews public health pesticides for their efficacy as well as their safety.[18] Thus, EPA requires registrants of such prod-

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[2] There is some indication that EPA's enforcement efforts are changing distributors' behavior. When EPA inspectors returned to the Chicago trade show in 1999, they found only minimal violations. According to an EPA official, the small number of violations at the 1999 show was a sign that industry has responded to EPA's enforcement efforts, but stated that this observation should be tempered by the fact that the vendors may have anticipated EPA's presence. Pesticide & Toxic Chemical News, Feb. 11, 1999.

[3] EPA Office of Enforcement and Compliance Assessment, FY98 Accomplishments Report (May 1999), at p. 54.

[4] In re McNeil-PPC, Inc., No. FIFRA-98-H-08, 1998 Westlaw 482777 (consent order July 31, 1998).

[5] In re Micro Pen of U.S.A., Inc., No. FIFRA-09-0881-C-98-06, 1999 Westlaw 362851 (EPA ALJ Mar. 22, 1999).

[6] *See* Daily Env't Rep. (BNA), Dec. 2, 1999, at A-6.

[7] EPA Region 4 Press Release (Oct. 15, 1999).

[8] EPA Region 1 Press Release (Oct. 5, 1999).

[9] EPA Region 2 Press Release (Nov. 10, 1999).

[10] 7 U.S.C. § § 136-136y.

[11] FIFRA § 2(u), 7 U.S.C. § 136(u).

[12] Public Law 104-170.

[13] FIFRA § 2(mm), 7 U.S.C. § 136(mm).

[14] FIFRA § 3(a), 7 U.S.C. § 136a(a).

[15] FIFRA § 14, 7 U.S.C. § 136l.

[16] FIFRA § 3(a)(1), 7 U.S.C. § 136a(a)(1).

[17] FIFRA § 3(c)(5), 7 U.S.C. § 136a(c)(5).

[18] FIFRA defines the term ''public health pesticide'' as ''any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for

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ucts to submit additional studies to demonstrate that such products are effective, i.e., that the products will do what their makers claim.[19] Among those pesticides that EPA considers to be ''public health'' products are those that claim to control ''microorganisms infectious to [humans] in any area of the inanimate environment . . . .''[20]

The ''Treated Articles'' Exemption

All products that make pesticidal claims must be registered by EPA unless they otherwise qualify for an exemption. EPA has carved out a very limited exemption for certain products that contain a registered pesticide that is included in these products to protect the products themselves. Such qualifying products are exempt ''from all provisions of FIFRA,'' including product registration requirements.

To qualify for the exemption, the pesticide that is added to the exempt product must be registered for that specific use and the treated product must be intended, and only be used for, the exempt purpose. Such products are called ''treated articles.'' This exemption is authorized by FIFRA Section 25(b)[21] and is codified in EPA's regulations, which state:

> *Treated articles or substances*. An article or substance treated with, or containing, a pesticide to protect the treated article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insect or fungus infestation), if the pesticide is registered for such use.[22]

EPA's regulation cites the following as examples of exempt treated articles: paint treated with a registered pesticide to preserve the paint coating, and wood products treated to protect the wood against insect or fungus infestation. Pesticides added to products for use in this manner generally are classified as ''preservatives'' and such pesticides have a variety of related uses in the manufacture of textiles, plastics, paper, adhesives, and coatings.

Although the Agency's regulations do not specifically say so, EPA takes the position that treated articles that make public health claims (such as ''kills germs'' or ''stops *E. coli*'') must be registered.

Registering Antimicrobial Pesticides

If a product that is subject to FIFRA does not qualify for the treated articles exemption, its maker (or distributor) must obtain a federal (and perhaps state) registration before marketing the product with antimicrobial claims. To date, EPA has issued only a very few registrations for treated articles making antimicrobial claims. In contrast, EPA has registered about 5,000 more conventional antimicrobial pesticide products (e.g., disinfectant solutions and sprays) containing one or more of 256 registered active ingredients.[23] However, until recent years, manufacturers and distributors that sought to register antimicrobial pesticides were faced not only with the costs of preparing the data required for registration, but also with EPA's poor track record in approving new antimicrobial active ingredients and end use products.

However, the FQPA, which amended FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA), included measures to encourage EPA to speed up its review process for antimicrobial pesticides. EPA responded in 1997 by creating a new division in the Office of Pesticide Programs called the Antimicrobials Division (AD), which oversees regulatory activity related to antimicrobial products, including product registration and re-registration. EPA has streamlined its review process and reports that the AD is meeting the goals established in the FQPA.

EPA has issued a proposed rule to implement the FQPA's provisions on antimicrobial pesticides.[24] In addition to establishing procedures for registration of antimicrobial pesticides, the rule would establish labeling standards for antimicrobial public health products, modify the notification process for antimicrobial products, and exempt certain antimicrobial products from regulation under FIFRA.

EPA Guidance–The ''Treated Articles'' Notice

Throughout most of the life of the Agency's pesticide regulatory program, EPA has issued documents called ''Pesticide Registration Notices'' (PR Notices) to inform pesticide registrants and other interested persons about important policies, procedures, and regulatory decisions. In some cases, PR Notices may go beyond this advisory function and at times have required registrants to amend their labels and occasionally their products' formulations. Such PR Notices have had virtually the same effect as regulations. Lawyers and some registrants have argued that these PR Notices violate basic principles of administrative law, since they are not subject to formal notice and comment rulemaking procedures. Therefore, in recent years, EPA has taken steps to increase opportunities for informal notice and public comment for more controversial PR Notices and has issued such Notices only after providing the regulated community with an opportunity to comment on a preliminary edition of the PR Notice.

Consistent with that approach, in April 1998, EPA released for public comment a draft PR Notice to clarify the criteria that pesticide products must meet to be eligible for the ''treated articles'' exemption.[25] The draft PR Notice stated EPA's interpretation that in order to qualify for the exemption, a product in question must be treated with a pesticide that has been registered specifically for protecting the treated product. Further, the draft stated EPA's position that distributors of such products may not make implied or explicit ''public health'' claims or ''esthetic'' claims.

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other recognized health protection uses, including the prevention or mitigation of viruses, bacteria, or other microorganisms (other than viruses, bacteria, or other microorganisms on or in living man or other living animal) that pose a threat to public health.'' FIFRA § 2(nn), 7 U.S.C. § 136(nn).

[19] 40 C.F.R. § 158.640(b)(1).

[20] Id.

[21] Section 25(b) provides that EPA may exempt from the requirements of FIFRA any pesticide that it determines to be ''of a character which is unnecessary to be subject to [FIFRA] in order to carry out the purposes of [FIFRA].'' 7 U.S.C. § 136w(b).

[22] 40 C.F.R. § 152.25(a) (parenthetical in original).

[23] National Agricultural Compliance Assistance Center, Pesticides Background Document (available at http://es.epa.gov/oeca/ag/tpes.html).

[24] 64 Fed. Reg. 50671 (Sept. 17, 1999).

[25] EPA Draft Pesticide Registration Notice, Eligibility of Pesticide Products For Exemption From Registration as Treated Articles Pursuant to 40 CFR 152.25(a) (availability announced at 63 Fed. Reg. 19256 (Apr. 17, 1998)).

The draft PR Notice clarified that any product that is treated with an unregistered pesticide, or that is distributed with esthetic or public health claims, must be registered by EPA before being distributed in the United States. Thus, applying the interpretations in EPA's 1998 draft PR Notice, if a marketing or label statement suggests to a consumer that the user of a treated article will derive any esthetic, health, or pesticidal benefits from the use of the product (other than enjoying the longer life of the protected product itself), then the treated articles exemption would not apply to the article, and the article would need to be registered with EPA. The draft PR Notice also provided guidance on label claims that EPA considers to be permissible for exempt treated articles.

The draft PR Notice was extremely controversial. The Agency received numerous public comments and took almost two years to review the comments received and issue a final PR notice. During the period since its release, the draft PR Notice was discussed at various EPA-Stakeholders meetings and a variety of fora sponsored by private groups.

After considerable deliberation, EPA announced on February 10, 2000 the release of its final version of the PR Notice interpreting the treated articles exemption.[26] Following is a discussion of some of the key issues raised and EPA's interpretation as articulated in the draft PR Notice and the Agency's final statement on those issues in the final PR Notice.

Public Health Claims

The draft PR Notice emphasized what EPA's enforcement actions have demonstrated: it has been EPA's long-standing interpretation (although not stated in the pertinent regulations) that the treated articles exemption does not apply to an article or substance claiming to be effective against public health organisms or claiming the ability to fight infectious diseases. EPA considers products bearing claims to control specific organisms (such as *E.coli* and salmonella) that may pose a threat to human health to be public health related pesticides. Not only does EPA require such products to be registered by the Agency, it requires the submission of specific efficacy data to support the public health labeling claims.[27]

In the draft PR Notice, EPA also stated that it would consider *any* use of the term ''antibacterial'' (and similar terms, such as antimicrobial, bactericidal, germicidal, etc.) in product claims to be a public health claim that would require the product to be registered. EPA stated that this interpretation would apply equally to the use of these terms either as part of the product name or within any other part of the labeling, related literature, or advertisements distributed in the marketing of the product.[28]

With one significant exception, the final PR Notice (designated PR Notice 2000-1) generally follows the policies discussed in the draft Notice concerning specific language that EPA believes constitutes public health claims. However, in an effort to make the final PR Notice more ''user friendly,'' EPA has included a list of the types of claims that it considers to be public health claims, including the following:

- claims for control of specific microorganisms or classes of microorganisms that are directly or indirectly infectious or pathogenic to man;
- claims for the product as a sterilant, disinfectant, virucide, or sanitizer;
- claims of ''antibacterial,'' ''bactericidal,'' or ''germicidal'' activity or references in any context to activity against germs or human pathogens that imply public health protection;
- claims for the product as a fungicide against fungi infections or fungi pathogenic to man, or the product does not clearly indicate it is intended for use against non-public health fungi;
- claims to control the spread of allergens through the inhibition or removal of microorganisms such as mold or mildew;
- non-specific claims that the product will beneficially impact public health by pesticidal means at the site of use or in the environment in which it is applied; and
- unqualified claims of ''antimicrobial'' activity.

As in the draft Notice, the final Notice states that use of the terms ''antibacterial,'' ''bactericidal,'' or ''germicidal'' will constitute a public health claim requiring registration. In contrast, the final Notice specifies that claims using the terms ''antimicrobial,'' ''fungistatic,'' ''mildew-resistant,'' and ''preservative'' may qualify for the treated articles exemption. However, products bearing these terms will not qualify if the terms are part of the product name and/or are not clearly qualified (''as to their intended non-public health use'').[29] Such qualifications must appear in the same location, type size, color, and prominence as the terms in question. It is significant that EPA has changed its original position on use of the term ''antimicrobial'' in the final PR Notice. However, EPA has provided no cogent explanation in the final PR Notice for drawing the distinctions it has between the terms antimicrobial and antibacterial.[30]

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[26] EPA Press Release (Feb. 10, 2000), noting the availability of PR Notice 2000-1, Applicability of the Treated Articles Exemption to Antimicrobial Pesticides (available from EPA's web site at www.epa.gov/opppmsd1/PRNotices).

[27] EPA generally does not require the submission of efficacy data prior to registration of products making non-public health claims, such as those relating solely to the esthetic protection of the article itself. However, the applicant must generate and keep supporting efficacy data on file to support these claims. *See* 40 C.F.R. § 158.202(i) and § 158.640(b).

[28] FIFRA defines product ''labeling'' to include printed or graphic matter which refers to the pesticide label. FIFRA § 2(p), 7 U.S.C. § 136(p). EPA has interpreted this to grant it authority to consider advertising in a variety of media as part of the *context* in which to interpret label claims when investigating potential FIFRA violations.

[29] The expression ''and/or'' is used here because the final PR Notice contains some ambiguity concerning whether these terms are completely prohibited from use in product trade names or whether they are permissible provided they are properly qualified by appropriate and proximate statements. *Compare, e.g.,* sections II.B.4 and IV.C of the final PR Notice 2000-1.

[30] Apparently, Agency staff were persuaded that consumers can perceive differences in the terms ''antibacterial'' and ''antimicrobial,'' and that ''antibacterial'' is distinctively a more health-related term.

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Non-Public Health Claims and Esthetic Claims

Some manufacturers incorporate pesticides into treated articles because of their ability to limit the growth of odor-causing bacteria or mold and mildew (which may discolor or stain a product). The preservatives help to maintain a more pleasing surface for the product user. For example, a shower curtain may be treated with a pesticide to limit the growth of mildew on or in the curtain. EPA's draft PR Notice implied that (in spite of long-standing industry practices of which EPA is aware) making the consumer aware that a product contains an ingredient for this esthetic purpose would not qualify for the treated articles exemption, since the benefits of the pesticide are primarily directed to the ''user'' of the treated article, rather than strictly for protection of the article. Applying the guidance in the draft PR Notice, one might conclude that incorporating an antimicrobial agent into an article of clothing to resist the growth of odors and to provide a ''fresher,'' more esthetically pleasing garment surface for the consumer might make the product ineligible for the exemption if its marketers described those benefits to the consumer.

The draft PR Notice's apparent prohibition on the use of esthetic claims raised serious questions for paint and coating makers, whose products often contain preservatives to enable the coating's surface to remain colorful and unblemished by mold or mildew even after the surface has dried. By suggesting in its draft PR Notice that EPA would prohibit claims regarding such ''esthetic'' attributes of a coating product, EPA signaled an apparent reversal of a long-standing policy that had been articulated in 1975 and followed by the industry and EPA staff ever since.[31] Pursuant to that 1975 policy, EPA had permitted use of 12 ''safe harbor'' statements (and minor variations) concerning paint and coating products.

After considering objections to the draft PR Notice from paint manufacturers and others, EPA has generally agreed to continue to apply its long-standing policy on the safe harbor statements for paint and coating products. Interestingly, and again without meaningful explanation, EPA's final PR Notice no longer refers to ''esthetic'' claims. Instead, the Agency has provided a list of claims that qualify as non-public health claims and that may be made for products that are eligible for the treated articles exemption.

The final PR Notices lists the following claims that qualify as non-public health claims:

- inhibits the growth of mildew on the surface of a dried paint film or paint coating;
- inhibits microorganisms that may cause spoilage or fouling of the treated article or substance;
- inhibits offensive odors in the treated article or substance; and
- as noted above, the use of terms such as antimicrobial, fungistatic, mildew-resistant, and preservative also apparently qualify as non-public health claims provided they are properly and prominently qualified as to their intended non-public health use.

Other Permissible Label Claims

Prior to issuance of the final PR Notice, treated article distributors watched with interest EPA pronouncements and enforcement actions concerning what appeared to be a moving target of acceptable label claims and required disclaimers.

The draft PR Notice provided specific guidance concerning acceptable language that EPA would permit to be included on treated article products without requiring the products to be registered. Thus, in 1998, EPA specifically stated that the use of the terms ''antibacterial,'' ''antimicrobial,'' ''germicidal'' and similar language in product labels or brand names would make the product ineligible for the treated articles exemption. Further, at the time it appeared EPA's position would be that to remain eligible for the treated articles exemption, label claims would be limited to (or necessarily include) minor variations of the following statement: ''This product contains a preservative (fungicide, insecticide) built-in (or applied as a coating) only to protect the product.''[32]

EPA's draft PR Notice stated that labels for exempt treated articles also would have to include enhanced qualifying statements in at least two situations. Specifically, labels for treated kitchen accessories and food contact articles such as a cutting board, high chair tray, or conveyor belt that could come into contact with food would need to be qualified with the following 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.'' The draft PR Notice also stated that labels on treated articles such as bed pans, bed sheets, and toilet seats that involve potential human contact with bodily fluids must be qualified with the following statement: ''This product does not protect users or others against bacteria, viruses or other disease organisms. Always clean and wash this product thoroughly before and after each use.''[33]

The final PR Notice is perhaps more deft, and appears to signal a somewhat more flexible approach than the draft PR Notice concerning acceptable labeling claims. However, the drafters of the final PR Notice inadvertently may have created some confusion about the use of ''public health'' terms in product names. Thus, in one section of the final PR Notice, EPA seems to be saying that any product name containing terms EPA considers to constitute public health claims *per se* will render the product ineligible for the treated articles exemption. However, EPA also states elsewhere in PR Notice 2000-1 that it will examine a product's name, its context, labeling claims, and other related elements on a case-by-case basis when determining eligibility for the exemption.[34] (It is equally possible that the ''flexibility'' in the final iteration of the PR Notice will both perplex

[31] 40 Fed. Reg. 28242 (July 3, 1975).

[32] However, settlements reached in various enforcement actions permitted the parties to use variants of the acceptable label statements described in the draft PR Notice.

[33] In addition, the preamble to the 1998 Federal Register notice that announced the availability of the draft PR Notice provided the following language *as yet another example* of an acceptable product claim that could be made until a final PR Notice might take effect: ''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.'' 63 Fed. Reg. 19256, 19257-58 (Apr. 17, 1998).

[34] *Compare, e.g.*, sections IV.C and III.B of the final PR Notice.

private sector marketing personnel and give great license to EPA enforcement staff.)

As an improvement over the draft PR Notice, the final PR Notice provides extensive, but not all-inclusive, lists of labeling claims that EPA considers acceptable and unacceptable under the treated articles exemption. The final PR Notice also provides examples of ''qualifying language'' to be used (apparently only upon products bearing claims including use of the terms antimicrobial, fungistatic, mildew-resistant, and preservative).[35] In spite of the ambiguities noted above, the Agency seems to be willing to accept the use of these terms as part of the product name when they are accompanied by the qualifying statements specified by EPA. Examples provided by EPA include: ''Antimicrobial properties built in to protect the product,'' and ''Provides mildew-resistant dried paint coating.'' The antimicrobial claim and the qualification statement must be proximate, and be given equal prominence.

Other Issues Addressed in the Final PR Notice

Pesticide additives must be registered for specific use. Like the draft PR Notice, the final PR Notice emphasizes that the pesticide used to preserve a treated article must be registered specifically for use in the article in order for the exemption to apply. While the draft PR Notice implied that EPA generally will require that the pesticide additive bear a label that specifies the article in question (e.g., for use to preserve ''shower curtains'' rather than to preserve ''plastics'' or ''polymers''), the final PR Notice specifically states that labels of the additive used in a treated article must ''include specific listings of the articles or substances that may be treated . . . such as toys, kitchen accessories and clothing . . . .''

This reflects EPA's approach when registering or amending the labels of such additives during recent years. It also reflects EPA's position that the use of a ''generic'' or unregistered imported analogue to a pesticide registered in the U.S. will not be sufficient for the finished article to qualify for the exemption. The final PR Notice provides no guidance concerning how EPA will implement this requirement and whether EPA will facilitate expedited review for makers of the registered materials preservatives who seek to conform their labels.

Registration of treated articles making public health claims. The final PR Notice reflects that apparently little or no progress has been made within the Agency since the publication of the draft PR Notice in determining what data will be required to support the efficacy claims for treated articles requiring registration. Thus, the final PR Notice reports that no established protocol exists for performing such studies, although such products will be required to meet the Agency's performance standard for other public health pesticides.

Effective date. Manufacturers and distributors of treated articles must bring their products, labeling, packaging, and advertising into compliance with the final PR Notice by February 11, 2001, although EPA encourages affected parties to come into compliance with the PR Notice 2000-1 as soon as possible. The final PR Notice states that until 2001, EPA is following the approach set out in its April 17, 1998 Federal Register notice.[36] Presumably, this means that EPA actively will continue to take enforcement actions against products that use terms and phrases that include explicit or implied public health claims (at least without appropriate, prominently placed, qualification statements).

Implications of the Final PR Notice

Although it provides a number of useful lists and phrases, the final PR Notice raises as many questions as it answers. The following are just some of those unanswered questions.

Implementation of the PR Notice may impose substantial burdens upon EPA, registrants, and the consumer products industry. The PR Notice will require certain manufacturers either to delete offending labeling claims or to register their consumer products as pesticides. Either option is potentially costly, especially if both the Agency and product makers are expected to complete these tasks by February 11, 2001. Minimally, EPA will be forced to spend time and resources to amend the labels of various registered preservatives that might not detail all of the end products in which they presently appear. It also is possible that EPA will need to review and register some very novel consumer products that are unlike any the Agency has registered before. This will draw resources away from more risk-relevant activities related to more conventional forms of ''pesticide'' products. EPA may have difficulty managing its potential workload without overburdening the existing product registration and re-registration programs.

This is especially true if the Agency is serious about resolving the difficult science and policy issues concerning efficacy testing. As EPA states in its final PR Notice, the Agency has no established protocols for the development of data to support public health claims on treated articles for which registration is sought. According to the PR Notice, the Agency expects to develop protocols as it works through the process of registering the articles. Most registrants are painfully aware of how difficult it can be to obtain EPA approval of new protocols for studies that are merely slight variations of guideline studies. Even if acceptable protocols can be developed, who will perform the studies: the maker of the additive or the end use product? Further, subtle shifts in product composition or in the proposed product's label claims might make study results inapplicable to the finished product? For example, will efficacy data generated perhaps by the registrant of the preservative on a polymer be considered acceptable on all forms (e.g., a cutting board *and* a band aid) of the finished articles that might be treated and distributed by its customers?

The final PR Notice does not address how treated articles that must be registered will be labeled. For example, will EPA expect that a toy will be labeled as a traditional pesticide? Is the traditional FIFRA label even appropriate for such products? Will such products have a ''signal'' word, a first-aid statement, and bear the traditional pesticide warning: ''keep out of reach of children''?

[35] It is not clear from the final PR Notice whether some form of a qualifying statement is a required feature for all treated articles, or only those using potentially problematic terms.

[36] 63 Fed. Reg. at 19257.

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Additional questions are raised by the interplay between EPA's interpretation of the treated articles exemption and the FFDCA's pesticide tolerance requirements. Products intended for use on food contact surfaces may require a tolerance or food additive regulation under the FFDCA. Although FDA and EPA have issued various statements concerning such requirements,[38] considerable clarification will be necessary before any one can say how the FDA and EPA will administer the requirement for tolerances for pesticide active *and* inert ingredients that become components of numerous treated articles that are intended for contact with food and food preparation surfaces.

EPA regulations prohibit the registration of a product for which appropriate tolerances or exemptions from tolerance requirements have not been issued.[38] If these issues cannot be resolved quickly, the February 11, 2001 deadline will soon become more imposing than it presently appears.

Other Federal and State Requirements

Manufacturers and distributors of FIFRA-exempt treated articles who may be breathing a sigh of relief now that the final PR Notice is available should not rest. They must continue to attend to their obligations under other federal and state requirements that are not affected by EPA's treated articles exemption.

As noted above, the FFDCA requires that substances that may reasonably be expected to become components of food must be specifically authorized for use in food contact articles, or otherwise permitted for such use. FDA traditionally has had jurisdiction over the components of such food-contact articles. However, when the article in question contains an antimicrobial preservative, the FDA's authority became less clear following enactment of the FQPA. In October 1998, EPA and FDA issued a joint notice to clarify their jurisdiction over antimicrobial substances and announced a planned rulemaking to articulate the agencies' respective authority.[39] However, shortly after the notice was issued, Congress enacted the Antimicrobial Regulation Technical Correction Act of 1998 (ARTCA),[40] which gives EPA the authority to issue regulations concerning the use of antimicrobial preservatives (and any inert ingredients used) in many food-contact articles. In July 1999, FDA released a guidance document to clarify its jurisdiction over antimicrobials used in or on food after enactment of the FQPA and ARTCA.[41] ARTCA and the Agencies' respective guidance provide a perilous landscape for makers and users of any ''materials preservative'' that may or may not have an intended, ongoing effect on part of a finished article that might contact food, food packaging, or a food preparation surface.

In spite of EPA's final guidance on what label claims for treated articles are or are not ''permitted,'' the Federal Trade Commission (FTC) requires that material claims made by manufacturers be truthful and substantiated.[42] The FTC has brought enforcement actions against a number of companies that have made unsubstantiated antibacterial or other germ-killing claims.[43]

Further, all states now require most pesticide end-use products to be registered with state authorities once a federal registration has been established. This raises the question of whether a product that is exempt from federal registration requirements will also be exempt from state regulation. It is conceivable that states that have not adopted the federal treated articles exemption could require registration of products that nevertheless qualify for the federal exemption.

Conclusion

PR Notice 2000-1 may be the most eagerly anticipated yet widely dreaded PR Notice in memory. Consequently, for days and weeks to come, lawyers, consultants, registrants and makers of treated articles will be sorting out the details of the Agency's pronouncement. For now, it is apparent that the light EPA may have shed upon the treated articles issue by the release of its final PR Notice seems dim in comparison to the glare of confusion still likely to be facing makers of additives and treated articles.

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[38] In 1999, FDA issued a guidance document to clarify its jurisdiction over antimicrobials. The FDA guidance document is discussed briefly below.

[38] 40 C.F.R. § 152.50(i).

[39] 63 Fed. Reg. 54532 (Oct. 9, 1998).

[40] Public Law 105-324.

[41] FDA, Antimicrobial Food Additives: Guidance (July 1999) (available at *http://vm.cfsan.fda.gov/ dms/opa-antg.html)*, availability announced at 64 Fed. Reg. 40612 (July 27, 1999).

[42] Section 5 of the FTC Act prohibits unfair or deceptive practices in or affecting commerce. 15 U.S.C. § 45(b). An advertising claim that is likely to mislead reasonable consumers in a material way is deceptive.

[43] FTC Division of Advertising Practices, Comments on EPA's Treated Articles PR Notice (July 17, 1998) (available at www.ftc.gov/be/V980017.htm).