

Pesticides, Chemical Regulation, and Right-to-Know Committee Newsletter

Vol. 5, No. 1

October 2003

FROM THE CHAIR

Kipp Coddington
Alston & Bird, LLP

The Pesticides, Chemical Regulation, and Right-to-Know Committee is looking forward to another busy year and we encourage you to play a role. To that end, we are seeking to fill one more leadership position – Vice-Chair for Membership. The Vice-Chair for Membership is responsible for managing the Committee's efforts to recruit new members and to welcome those that have joined. These functions are critically important for the Committee. Please contact me at kcoddington@alston.com or 202/756-3408 if you are interested in the position.

The Committee will be co-sponsoring a panel at the 33rd Annual Conference on Environmental Law (Keystone), to be held March 11-14, 2004. Along with the Agricultural Management Committee, we will host a program entitled "21st Century Agricultural Nuisances." The program will cover three areas: (1) claims related to pesticide drift, (2) nuisance and airborne toxic claims associated with concentrated animal feeding operations, and (3) off-site liabilities associated with the approved or unapproved use of genetically modified or biotechnology crops. We anticipate having speakers from USDA, CropLife America, and other affected

organizations. Practitioners in the agricultural, water and pesticides areas will find this panel to be challenging, thought-provoking and practical.

In the coming weeks, and in addition to the Keystone program discussed above, the Committee will announce its program schedule for the coming year. In addition to our ongoing Washington, D.C.-based programs on pesticides (led by Ken Weinstein) and chemicals (led by Herb Estreicher), we intend to hold teleconferences or in-person programs on the following topics:

- Role of the new Department of Homeland Security (DHS) in setting and enforcing chemical and biological clean-up standards. DHS intends to have primary authority over the federal government's response to toxic release emergencies. DHS is also developing clean-up standards for dirty-bomb attacks. Both of these activities raise interesting jurisdictional issues vis-à-vis EPA, DOE, and other government agencies and departments.
- Status of the DOJ's new enforcement initiative against hazard materials shippers and carriers. On Sept. 30, the Attorney General announced that Emery Worldwide Airlines had agreed

**Pesticides, Chemical Regulation, and
Right-to-Know Committee Newsletter
Vol. 5, No. 1, October 2003
Lynn L. Bergeson, Editor**

In this issue:

From the Chair
Kipp Coddington..... 1

EPA's Role in the Regulation of Anti-
microbial Pesticides in the United States
Frank T. Sanders 3

EPA's Ongoing Antimicrobial Efficacy
Testing Program
Lawrence E. Culleen 9

It's Time to Change EPA's Treated
Article Exemption
Michael T. Novak, Esq. 11

Over-Reaching in the Regulatory
Arena: Europe Tackles Chemicals
Michael P. Walls..... 12

Want to Get Wet and Dirty? Join Our
Public Service Effort!
Alexandra Dapolito Dunn. 14

New from ABA Publishing 16

© 2003. American Bar Association. All rights reserved. The views expressed herein have not been approved by the ABA House of Delegates or the Board of Governors and, accordingly should not be construed as representing the policy of the ABA.

This newsletter is a publication of the ABA Section of Environment, Energy, and Resources, and reports on the activities of the committee. All persons interested in joining the Section or one of its committees should contact the Section of Environment, Energy, and Resources, American Bar Association, 750 N. Lake Shore Drive, Chicago, IL 60611.



to pay a \$6 million fine for violations of the federal hazmat laws. *U.S. v. Emery Worldwide Airlines Inc.*, No. CR-3-03-113 (S.D. Ohio Sept. 17, 2003). The settlement marks the first blow in DOJ's heightened enforcement scrutiny of hazmat issues in the post 9/11 environment.

- Status of the chemical security legislation that is currently working its way through Congress. At issue are two key issues: (1) which agency will have primary authority over plant security and (2) whether and the extent to which companies will be required to use safer and less-toxic substances in their processes.

Please let me know if you are interested in helping with these programs. We also are eager for ideas for additional programs from the membership.

**EPA'S ROLE IN THE REGULATION
OF ANTIMICROBIAL PESTICIDES
IN THE UNITED STATES**

**Frank T. Sanders
Director, Antimicrobials Division,
Office of Pesticide Programs,
U.S. Environmental Protection Agency**

Introduction

It is often surprising to the general public, health care professionals and others that many products used to kill microorganisms in various settings such as hospitals, dental offices, clinics, industrial manufacturing plants, homes, workplaces, and other sites are considered antimicrobial pesticides and are regulated by the U.S. Environmental Protection Agency (EPA). This is because certain antimicrobial agents (disinfectants,

sanitizers and some sterilants) are regarded as pesticides because of their intended uses. EPA regulates pesticides under the statutory authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Any person intending to manufacture, distribute or sell an antimicrobial pesticide in the United States must obtain a registration for that product. In addition, all antimicrobial pesticides registered before Nov. 1, 1984, must be reregistered with EPA to ensure they meet current standards.

EPA's responsibility for regulating pesticides is a critical element of its mission to protect public health and the environment. As defined in FIFRA, the term **pesticide**, among other things, encompasses any substance or mixture of substances "intended for preventing, destroying, repelling, or mitigating any pest" The term pesticide does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in Section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. § 321). These products are regulated by the Food and Drug Administration's (FDA) Center for Devices and Radiological Health.

As defined under FIFRA, the term **pest** means "(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-organisms (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest" FIFRA further defines the term **antimicrobial pesticide** to mean "a pesticide that is intended to (1) disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms; or (2) 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 in the intended use is exempt from, or otherwise not subject to, a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act."

EPA has regulatory authority under FFDCA as well as under FIFRA for pesticides used on or in food. Thus, pesticides used on food or food contact surfaces need to meet requirements of both FIFRA and FFDCA. Under FFDCA, food cannot be sold if it is adulterated. A food is considered adulterated if, among other things, it contains unsafe amounts of a pesticide residue. EPA has the authority to determine the maximum amount of pesticide residue (tolerance) allowed in foods to ensure that the food is not adulterated. FDA enforces the pesticide tolerances that EPA sets.

FIFRA allows EPA to regulate three characteristics of pesticides: chemical composition, labeling and packaging. EPA registers pesticide products based on data showing that there will be no "unreasonable adverse effects" to man or the environment if the pesticide is used according to the directions on the label. FIFRA grants EPA several additional authorities. The agency can require certification of pesticide users. Also, FIFRA is one of the few statutes with data call-in authority, which allows EPA to require certain kinds of post-registration data. Furthermore, unlike other EPA statutes, FIFRA requires decision-makers to consider not just risks, but the balance between risks and benefit when making a regulatory decision (economic, environmental, health, etc.).

Laws Governing the Regulation of Antimicrobials

There are four major laws which govern how antimicrobial products are regulated. They are (1) FIFRA, (2) FFDCA, (3) the Food Quality Protection Act (FQPA) and (4) the recently

passed Antimicrobial Regulation Technical Corrections Act (ARTCA).

FIFRA was first passed in 1947 to regulate the sale distribution, use and disposal of pesticides but did not provide authority to deny registration until 1964. FIFRA is the main law EPA operates under for the registration of all pesticides, including antimicrobials.

FFDCA regulates the use of drugs and chemicals in cosmetics and in human and animal foods. FFDCA also establishes the amounts of pesticide residues that are allowed in foods and in animal feed. FFDCA monitors and enforces tolerances or exemptions from tolerance of pesticide residues on food and animal feed. FFDCA § 408.

On Aug. 3, 1996, FQPA was enacted, modifying both FIFRA and FFDCA. Most of its provisions were effective immediately, although some require implementing regulations. FQPA established goals to protect the public, especially children, from exposure to harmful pesticides in foods. The law also required EPA to treat antimicrobial pesticides separately and to streamline the registration process for non-food antimicrobial pesticides.

ARTCA was enacted by Congress on Oct. 30, 1998, to modify FFDCA to effectively transfer authority over a number of pesticide residues to FDA. Regulatory authority over these residues had originally been transferred to EPA by FQPA.

Classification of Antimicrobial Pesticides

EPA classifies antimicrobial pesticides into two major categories, those that are considered to be related to public health and those that are non-public health related. Public health related antimicrobial products have various levels of activity all of which require the submission of product specific efficacy data as a part of their application. These products are

intended to kill, inactivate or reduce microorganisms on inanimate objects, surfaces or other media. Antimicrobial agents used on or in the living body of man or animals are regulated by the FDA under the statutory authority of the FFDCA.

The following are some examples of pesticides which are registered by EPA with the intent of providing a public health benefit, therefore requiring efficacy data as a condition of their registration:

- Disinfectants used in hospitals and other health care settings on floors, walls, medical equipment surfaces and other inanimate, environmental surfaces.
- Household products which may have disinfectant or sanitizing activity.
- Products intended for use in municipal water systems or for emergency drinking water applications.
- Products which are intended to disinfect water in swimming pools and hot tubs.
- Sanitizers which are used in food handling establishments as final sanitizing rinses on surfaces, objects, equipment, and other items which come into contact with food. Because these sanitizing rinses are used on surfaces which come into contact with food, in addition to the requirement of efficacy data, food contact sanitizing rinses require the setting of a tolerance or an exemption from the requirement of a tolerance.

Examples of pesticides which do not require the submission of efficacy data as they are not intended to provide a “public health” benefit as defined by the EPA Public Health initiative, but

require registration under FIFRA are as follows:

- Products intended to control slime-producing microorganisms in recirculating cooling water systems, such as cooling water towers, cooling water in brewery pasteurizers, and canning operations, and water rinses for raw agricultural commodities.
- Specialty preservative products, such as wood preservatives, in can preservatives for paints, preservatives for metal working fluids and cutting oils, adhesives, fuel, fabrics, textiles and other materials.
- Household products which inhibit the growth of odor-causing bacteria, and other products which may inhibit the growth of microorganisms that may cause spoilage on food.

Products used to disinfect veterinary/animal premises and which are used against organisms that are strictly animal pathogens with high economic impact, such as the etiological agent of foot and mouth disease, may require some presumptive evidence of product efficacy. The registration of animal premises disinfectants is usually handled on a case-by-case basis and is based on intergovernmental communication with the U.S. Department of Agriculture (USDA).

This list is not meant to be all inclusive – the reader is advised to consult a member of the product management teams or the microbiologists in the Product Science Branch of EPA’s Office of Pesticide Programs (OPP), Antimicrobials Division if he/she requires additional information on these category distinctions (703/308-6411).

Levels of Activity for Public Health Related Antimicrobial Products

The heart of a registration application for public health related antimicrobial pesticides involves the product’s label claims and the specific level of activity the proposed registrant intends to achieve with their product. EPA recognizes three major groups of public health related antimicrobial products that differ in the level or completeness of antimicrobial activity to be achieved:

- *Sterilizers*: Sterilizers destroy or eliminate **ALL** forms of bacteria, fungi, and their spores, and viruses. Spores are considered the most difficult form of microorganism to destroy. Thus the term sporicide is synonymous with sterilizer. Sterilizers can be in the form of liquids, gases, or vapors. Liquid chemical sterilants which are used to reprocess critical or semi-critical medical devices are regulated by FDA.
- *Disinfectants*: Disinfectants destroy or irreversibly inactivate infectious, or other undesirable organisms, but not necessarily their spores. Disinfectants can be concentrated liquids, ready-to-use liquids, powders, or sprays. There are three types of disinfectant products that EPA registers based upon submitted efficacy data: (1) limited, (2) general or broad-spectrum and (3) hospital disinfectants.
 - *Limited*: When a disinfectant is recommended in labeling for use against only a specific major group of microorganisms (such as gram-negative or gram-positive bacteria), it is considered to have only limited effectiveness. For example, some pine oil toilet bowl products are effective only against gram-negative bacteria.

- *General or Broad-spectrum:* When a disinfectant is represented in labeling as having a broad spectrum of activity against both gram-negative and gram-positive microorganisms, more extensive testing is required. Many household disinfectants fall into this group in addition to swimming pool products and water purifiers.
- *Hospital Disinfectant:* When a disinfectant is represented in labeling for use in hospitals, clinics, dental offices or any other medical-related facility, it must show effectiveness against both gram-negative and gram-positive microorganisms in addition to showing effectiveness against *Pseudomonas aeruginosa*, the organism responsible for most nosocomial infections (hospital-borne infections). A registrant who wants to market a hospital disinfectant as a virucide must provide data to EPA showing the product is effective against each specific virus the company wishes to list on its label. Similarly, a registrant that wants a product approved as a tuberculocide must show that the product is effective against a *Mycobacterium* that EPA accepts as a surrogate for the actual tuberculosis bacterium.
- *Sanitizers:* Sanitizers reduce but do not necessarily eliminate all the microorganisms on a treated surface. EPA registers many types of sanitizers, *i.e.*, sanitizers for non-food contact surfaces, previously cleaned food contact surfaces, and products possessing residual self-sanitizing activity. To be a registered sanitizer, a product's test results must show a reduction of 99.9 percent (for non-food

contact sanitizers) and 99.999 percent (for food contact sanitizing rinses) in the number of each test microorganisms over the parallel control. Sanitizers can be liquids, powders or sprays. Prior to the passage of FQPA and the resulting amendments to FIFRA, acceptable residue levels for food contact sanitizing rinses were determined by FDA and end use formulations which had been cleared for use as food contact sanitizing rinses were listed under 21 C.F.R. Section 178.1010. EPA is now responsible for establishing tolerances or granting exemptions from tolerance under FFDCa Section 408.

Types of Registration Actions

Basically antimicrobial pesticide registration actions fall within five major categories: "New Active Ingredient" registration, "Major New Use" of a registered chemical, registration of a product which is identical or substantially similar to an existing product (also known as a "Me-Too"), "Other New Products," and "Amendments" to registered products. Over the past two years, however, the Antimicrobials Division has also had to issue crisis exemptions for the use of several products that were used in premise decontamination in order to prevent the spread of foot and mouth disease. Post 9/11 activities also found the Antimicrobials Division in the midst of decontamination and remediation efforts following anthrax incidents on Capitol Hill and at various postal and private facilities across the country. In both of these cases, manufacturers were required to demonstrate that their proposed products were efficacious prior to being granted an exemption. While this was a departure from routine procedures, the Antimicrobials Division had to make certain that products provided for remediation and disinfection were safe and effective when used in accordance with the conditions of the crisis exemption.

Ensuring Efficacy of Disinfectants and Sanitizers

More than 50 percent of antimicrobial pesticides are considered to be public health related products, intended to control disease-causing microorganisms such as *E. coli*, HIV, and the tuberculosis bacterium. EPA reviews public health antimicrobial pesticides for efficacy as well as safety for two major reasons. First, if these products are ineffective, people may get sick or remain sick longer, potentially leading to avoidable public health problems. Second, unlike larger pests such as weeds and weevils, microorganisms are not visible to the naked eye, and users cannot generally determine whether products are working. Therefore, EPA expends significant resources in evaluating test methods and determining performance standards to ensure that public health antimicrobials work as they claim and actually protect the public's health. The Antimicrobials Division also supports experimental studies to develop new methods for testing and validating the efficacy of antimicrobials. The public health related label claims on all antimicrobial pesticides must be supported with product specific efficacy data. The complete data requirements are outlined in 40 C.F.R. Part 158, however, following is a description of the requirements to secure a basic disinfectant claim. To satisfy a limited (against gram positive or gram negative bacteria) disinfectant claim, the applicant must submit data against either *Staphylococcus aureus* or *Salmonella choleraesuis*. A general or broad spectrum disinfectant claim requires data to be submitted against both *Staphylococcus aureus* and *Salmonella choleraesuis*. A hospital disinfectant claim requires the addition of *Pseudomonas aeruginosa* to the broad spectrum data requirement. It is recommended that the reader consult members of the Product Science Branch for detailed explanations of the product specific efficacy data requirements.

EPA has also established a antimicrobial testing program to ensure the efficacy of antimicrobial products and in turn increase public safety by reducing health risks associated with product performance failures. To date, all of the sterilant products have been tested, along with approximately one-third of the registered tuberculocidal products and approximately 12 percent of the registered disinfectants. EPA anticipates that the testing of hospital disinfectants will be completed in the next five to six years.

Role of Antimicrobials in Preventing Foodborne Infections

Antimicrobial pesticides play a major role in preventing foodborne diseases which have increased at an alarming rate in recent years. Approximately 1,000 antimicrobial products are registered for use as disinfectants, sanitizers and preservatives on food and food contact surfaces. The primary use of antimicrobial agents in the food and food contact arena is to control organisms that cause human disease. Disinfectants and sanitizers must satisfy strict efficacy performance standards prior to being registered by EPA for use. Preservatives, including bacteriostats which prevent bacteria from reproducing, are primarily designed to prevent spoilage or discoloration of food, however. These products are not considered public health pesticides and are reviewed for product safety, but not usually for product efficacy.

New Challenges for the Antimicrobials Division

Emerging Pathogens

In the last year, the Antimicrobials Division has had to address a number of emerging pathogens which posed new threats to public health safety. The Antimicrobials Division has worked in concert with other lead government agencies such as the Centers for Disease

Control and Prevention and USDA to address these emerging pathogens and aided in the development of documents addressing the disinfection of contaminated premises which may serve as reservoirs for future infections. Specifically, the Antimicrobials Division provided pivotal information on antimicrobial products that would likely be effective for inactivating (on contaminated surfaces) the pathogens responsible for avian influenza, monkey pox, and foot and mouth disease in animals and the Norwalk virus and severe acute respiratory syndrome (SARS) virus in humans.

Prion diseases, specifically chronic wasting disease which appeared in deer and elk, was another in the emerging pathogen category. These diseases are caused by a non-living protein material that is infectious but is extremely difficult to inactivate. To make matters more complicated, prion diseases are slow in their onset and may be difficult to diagnose. EPA/Antimicrobials Division is currently in the process of determining how products which bear claims of prion inactivation will be regulated and how studies to determine efficacy of products for prions should be designed.

Homeland Security

Following the attack on Sept. 11, 2001, the Antimicrobials Division has been actively involved with other agencies in developing a process that should be followed if biological agents are used to threaten the security of the citizens of the United States. The Antimicrobials Division has participated in workshops and provided information that will be useful to first responders in the event of an episode of significance. The process developed and the lessons learned from the decontamination and remediation of buildings following the anthrax incidents are currently being modified and will ultimately serve as a template if similar events occur in the future.

The Antimicrobials Division has been proactive in promoting interagency collaborative research on methods and surrogates for testing the efficacy of antimicrobials against anthrax spores, developing registration data and labeling requirements for antimicrobials that would claim to be effective against bio-warfare agents, and in working with other agencies to be better prepared for preventing and/or responding to the use of bio-threat agents.

New Approaches for Old Pests

Historically, EPA has dealt with mold, mildew and slime from a more aesthetic perspective; however, new information and scientific data have led EPA to revisit its past policies and consider the new information on these pests and the possible threat to human health. EPA is considering the requirement of having efficacy data provided for products having mold and mildew claims. In addition, EPA may require that additional actions be performed by the user and that the language on the label be expanded to address human health concerns.

Slime has been subdivided into two categories; those having no impact on public health and those having public health implications. The former category would include industrial slime; the latter category would include biofilms, such as those found in bathrooms, spas and hot tubs and in dental unit water lines. Because of the complex nature of biofilms, the Antimicrobials Division recognizes that the efficacy observed when disinfectants are used on planktonic cells, may not automatically predict the degree of efficacy when dealing with microbial populations embedded in an extracellular matrix. The Antimicrobials Division is currently involved in developing protocols and establishing standards for determining the efficacy of products proposed for use against biofilms.

Summary

The Antimicrobials Division has set ambitious goals to continue to protect public health and the environment, while improving service to registrants and other stakeholders. EPA will expand its post-registration efficacy testing of tuberculocides and other hospital disinfectants with the opening of its new testing laboratory in Ft. George G. Meade, Maryland. This activity is crucial to ensuring that public health pesticides remain effective after they are on the market. Outreach and cooperative interagency activities are also expanding, especially in preventing food borne infections and preventing hospital-acquired infections. These illnesses each cost the United States billions of dollars annually in direct and indirect medical costs. EPA is participating in several interagency food safety activities, and is increasing its contacts with industry and consumer associations, as well as with FDA and USDA. To enhance its role in preventing hospital-acquired infections, EPA is also working closely with health and user groups, state and local organizations, and the Occupational Safety and Health Administration (OSHA) and FDA.

There are numerous variables and issues which effect the registration of antimicrobial products, and EPA must constantly balance them in accordance with its primary mission of protecting human health and the environment. This article has provided a broad summary of some of the regulatory and scientific requirements, challenges and highlights of registering disinfectants, sanitizers and sterilants with EPA. Because the antimicrobials market is a fast moving and highly competitive arena with new technologies and issues constantly developing, however, new policies and procedures are often on the horizon. Therefore, for more information, individuals should refer to the referenced material for complete and current information on policy, procedures and requirements.

EPA'S ONGOING ANTIMICROBIAL EFFICACY TESTING PROGRAM

Lawrence E. Culleen
Arnold & Porter
Washington, D.C.

More than one decade after receiving stinging criticism from the General Accounting Office (GAO) concerning a central element of its pesticide registration program, the U.S. Environmental Protection Agency (EPA) still has not completed its effort to confirm the efficacy of antimicrobial products that make public health claims.

In 1990, GAO issued a scathing report which faulted EPA's Office of Pesticide Programs (OPP) for shortcomings in its programs for registering and monitoring the effectiveness of antimicrobial pesticides. GAO/RECED-90-139 (Aug. 1990). Pesticides are subject to EPA's jurisdiction pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Antimicrobial pesticides are a special class of pesticides which are marketed with claims that they (among other things) disinfect, sanitize, reduce or mitigate microbiological organisms. FIFRA § 2(mm). Although pesticides generally must be registered with EPA before they can be distributed in the United States, antimicrobial products that claim to be effective against human pathogens also must be demonstrated to be effective before such claims may appear on any label in U.S. commerce. FIFRA § 3 and 40 C.F.R. § 158.640. When GAO issued its report in which some of the core elements of EPA's antimicrobial registration and efficacy programs were challenged, the agency commenced a process by which it would test previously-registered antimicrobial products in accordance with a priority system based upon the potential risks to the public from efficacy failures (*i.e.*, EPA would test sterilants first, then tuberculocides, and subsequently then hospital disinfectants). Due to overlapping

jurisdiction, EPA was expected to coordinate with numerous other federal agencies such as the Food and Drug Administration and the Centers for Disease Control and Prevention. Simultaneously, EPA planned to make improvements to its prescribed efficacy test methods in order to respond to criticisms concerning the scientific validity of that aspect of its program.

During the early 1990s, EPA made projections that it would complete its antimicrobial efficacy program improvements by the end of the decade. During a June 2003 conference at which a project update was given to the public by senior OPP program managers, however, it became clear that EPA will fall far short of that goal. Budget shortfalls, staffing needs and the complexity of the task have slowed EPA. Thus, EPA reported that since it began the program, the agency has tested all of the registered sterilant products (finding a 50 percent failure rate), 40 percent of the tuberculocides, and only 12 percent of the hospital disinfectants.

To date, EPA has worked not only with other federal agencies, but also with a variety of laboratories, with EPA's regional staff, and with certain state pesticide registration officials to cobble together improvements to its antimicrobials efficacy program. Furthermore, EPA has provided funding to public and private researchers in support of its efforts to improve test methods. Perhaps most notably, EPA's product registration staff has been working closely with the agency's enforcement arm to ensure that products which fail efficacy testing are subjected to visible agency intervention.

FIFRA provides EPA with the opportunity to bring an immediately-effective action against companies with products which fail antimicrobial efficacy testing. Thus, when EPA has obtained data showing efficacy failures for certain kinds of "public health" products, the

agency has issued a Stop Sale, Use or Removal Order (SSURO) pursuant to Section 13(a) of FIFRA. The Act authorizes use of these orders whenever EPA merely has a "reason to believe on the basis of an inspection or test that such pesticide or device is in violation" of FIFRA. Furthermore, a SSURO can be issued to any person (such as a retailer or distributor) who has custody of such a pesticide. Thus, in antimicrobial product failure cases, EPA has used SSUROs to effectively force the recall of an affected product until such time as new efficacy data and/or alternative label claims can be submitted to the agency, reviewed by EPA staff scientists, and agreed upon by the registrant and the agency. Needless to say, that is a resource-intensive exercise for both EPA and the registrant.

It is not clear how long it will take EPA to complete its efficacy testing program for public health antimicrobial products. Nor is it clear when EPA will resolve all of the serious technical and scientific challenges to its present efficacy testing methods. Given the failure rate EPA has seen for the products tested thus far (when EPA is using its own methods and laboratory personnel), however, it is likely that enforcement actions will continue to be forthcoming from EPA.

Larry Cullen practices law in the Washington, D.C. offices of Arnold & Porter. Prior to entering private practice, Larry served in a variety of management positions within EPA's Office of Prevention, Pesticides and Toxic Substances.

ABA Section of Environment, Energy, and Resources

33rd Annual Conference on Environmental Law

March 11-14, 2004

Keystone, Colorado

SAVE THE DATE!

IT'S TIME TO CHANGE EPA'S TREATED ARTICLE EXEMPTION

Michael T. Novak, Esq.
Keller and Heckman LLP

It is often said that mankind's technological "know-how" doubles every two years. This adage might apply, as well, to the antimicrobial pesticide industry, as many novel products are being developed to better protect consumers from bacteria, fungi, viruses and other microorganisms. These promising new technologies include antibacterial kitchen sponges and towels designed to minimize bacterial and mold growth, antibacterial shower curtains and paints that prevent the growth of mildew, thereby reducing allergen exposure, and antibacterial surgical masks and gowns that reduce nosocomial infection in hospitals. The marketing of these products has been frustrated, however, by the U.S. Environmental Protection Agency (EPA), the agency charged with regulating the products under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Put simply, EPA has made it impossible to register these products as pesticides. Because EPA's mission, in part, is to promote and protect the public health, perhaps it is time to expand FIFRA's treated article exemption, which exempts from pesticide regulation certain manufactured goods or articles treated with pesticides, to include treated articles that provide public health benefits.

With limited exception, EPA must register as a pesticide any product sold or distributed in the United States for the purpose of controlling bacteria or other microorganisms. EPA has registered, however, few pesticide-treated articles designed to protect humans, as the agency has not issued standard protocols to measure efficacy, instead requiring development by applicants, an expensive and time-consuming process. Further, to register a public health-treated article, EPA requires that

applicants demonstrate a log reduction in test organisms equivalent to conventional sanitizers or disinfectants, an unworkable standard given that most antimicrobials in treated articles release slowly or are bound to the article's matrix. As a result, products that benefit public health are not being marketed because of the expense, time and uncertainty in gaining EPA approval.

Yet, EPA currently exempts from FIFRA regulation certain articles treated with pesticides. Under the treated article exemption (40 C.F.R. § 152.25(a)), any article containing an EPA-registered pesticide solely to protect the article itself is exempt from FIFRA regulation. To meet the exemption, pesticidal claims accompanying the product must be restricted to article protection rather than providing pesticidal benefit to humans (*i.e.*, benefits outside the article itself). EPA promulgated this exemption, in part, to avoid the burdensome task of separately registering every article that contains a pesticide. Must the exemption necessarily apply to pesticidal claims that protect the article itself? Why should it not apply, as well, to articles that provide some measure of public health protection?

EPA should amend the treated article exemption to permit a defined, yet limited, category of public health claims. EPA can adequately protect the public from inefficacious articles through its regulation of the antimicrobial active ingredient applied to the article, which it must register as a pesticide. EPA need only determine that the active ingredient in the article provides some public health benefit, and should not require efficacy data equivalent to a sanitizer or disinfectant. The scope of the public health claims would be determined by EPA, and would need to be properly qualified so as not to mislead the consumer. For example, a shower curtain impregnated with an antimicrobial might state the following: "This

product contains an antimicrobial to control mold and mildew on the curtain, thereby reducing exposure to associated allergens. This product may not eliminate all mold and associated allergens.”

The average consumer is intelligent enough to understand this claim. In many cases, treated articles are effective in providing a more hygienic environment, yet are not designed to protect the user from all known pathogens. Although EPA rulemaking can be a time-consuming process, it will take less time than it currently takes for EPA to approve a treated article efficacy protocol. By expanding the treated article exemption, EPA could adequately regulate public health articles while facilitating the marketing of promising new technologies that, under the current system, may never see the light of day on a grocery store shelf.

For more information on this issue, please contact the author Michael T. Novak at Novak@khlaw.com.

OVER-REACHING IN THE REGULATORY ARENA: EUROPE TACKLES CHEMICALS

**Michael P. Walls
Senior Counsel,
American Chemistry Council
Arlington, Virginia**

Editor’s Note: On Sept. 17, 2003, another version, referred to as the Interservice Draft, of the EU Commission’s REACH proposal, was circulated. Although changes intended to ease the burden on industry have been proposed, other aspects of the new draft expand REACH requirements, and many believe the proposal remains unacceptable because it is unworkable. The article below outlines the earlier, May 7, version of the legislation.

Introduction

On May 7, 2003, the European Commission published on the Internet its 1,200 page proposed regulation to implement a new European chemicals policy, known as REACH (for **R**egistration, **E**valuation, and **A**uthorization of **C**hemicals). See <http://europa.eu.int/comm/enterprise/chemicals/chempol/whitepaper/reach.htm> for additional information on the proposal.

The proposed regulation has drawn praise from some public interest quarters and criticism from the business community and foreign governments, largely due to the burden, cost and practical difficulties inherent in the proposal. The U.S. Government’s submission summarized the concerns raised by the proposal: “[T]he European Commission’s draft chemicals regulation appears to adopt a particularly costly, burdensome, and complex approach, which could prove unworkable in its implementation, adversely impact innovation and disrupt global trade. The proposal . . . raises fundamental questions about its workability – and thus its ability to effectively achieve its health and environmental policy objectives.”

Elements of the REACH Proposal

Registration: All chemicals produced or imported in amounts greater than 1 ton per year must be registered. Registrations are to include a detailed technical dossier on chemical hazards, uses and exposures, with incrementally more data required for those chemicals at the higher volume levels. Registrations must also be accompanied by a risk assessment, to include a comprehensive assessment of hazards, exposures and risks, based on “exposure scenarios” that address the registrant’s own use and all intended uses (at least 90 percent of the known uses, according to the draft). “No-effect” levels for health and environmental impacts are to be

established by the registrant for all relevant human populations and all environmental media. Safety reports are intended to demonstrate that risks of the chemical in production and use are adequately controlled.

Evaluations: Individual member governments of the European Union will evaluate the registration dossiers to determine the sufficiency of the data submitted with the registration, as well as any proposed plans to fill identified data gaps.

Authorization: The authorization system imposes a use-specific licensing program for chemicals that demonstrate certain hazard characteristics, namely carcinogens, mutagens and reproductive toxins (CMRs); persistent, bioaccumulative and toxic (PBT) substances; and very persistent or very bioaccumulative (vPvB) substances. Authorization constitutes a separate regulatory track independent of regulation, although substances that have gone through registration and evaluation could be identified as future candidates for authorization.

Restrictions: Additional restrictions on the manufacturing, use or sale of a substance can be proposed by the individual governments or by the Commission, on the basis of a review of exposures, risks, socio-economic benefit and the availability of substitutes. This is a process separate from authorization.

Exemptions: The draft regulations establish limited exemptions from registration and authorization. Some exemption criteria differ significantly from those generally harmonized at the international level (e.g., polymers), others (e.g., intermediates) appear to discriminate against imports. Other exemptions (e.g., a 5-year exemption for process oriented research and development, with a possible 5-year extension) may be too limited to be of practical value. No *de minimis* exemption is provided.

Downstream Impacts: The draft regulations apply to the downstream users of chemicals and chemical products. Downstream users are required to compile a Chemical Safety Report, even when the manufacturer or importer has registered a chemical, and must provide an assessment even for unregistered chemicals used in amounts greater than 250 kilograms per year. Downstream users may have to register chemicals if their specific uses are not covered by the manufacturer/importer's registration, and may be required to apply for use-specific authorizations.

Concerns Raised by REACH

According to the European Commission (Commission), "thousands" of comments were filed in response to the public comment period which ended July 10, 2003. Comments (available on the Web site noted previously) generally address the following issues:

- Increased testing requirements imposed by the proposal.
- Strong expressions of support from many public interest groups.
- Business and governments raised concerns about the practical workability, costs and burden of the proposal, as well as the impact of REACH on the European Union's obligations under the World Trade Organization agreements.
- Downstream users and worker interests raised concerns about the effect the regulation would have on their businesses and jobs.

The Commission is expected to consider the comments during the next 6 to 8 weeks, and may submit a revised draft for consideration in late September or early October. Even if the Commission's work is completed in that timeframe, the European Union's Parliament

and Council would not likely approve the proposal until late 2004 or early 2005. A new regulation could be expected to go into effect, therefore, sometime in 2005 or 2006.


Michael P. Walls is Senior Counsel, American Chemistry Council, Arlington, Virginia. He may be reached at Mike_Walls@americanchemistry.com. The views expressed are the author's and do not necessarily reflect the views of the Council or its members.

WANT TO GET WET AND DIRTY? JOIN OUR PUBLIC SERVICE EFFORT!

Alexandra Dapolito Dunn
Co-Chair, In-House Counsel Committee
adunn@amsa-cleanwater.org

The Section's In-House Counsel Committee invites you to join our exciting community service project with *Earth Force – Youth for a Change!* This article gives you a brief overview of our efforts to date, and provides information on how you can get involved in our activities. Earth Force is a national non-profit organization created in 1994 by The Pew Charitable Trusts in recognition of two emerging national trends: young people's desire to act on behalf of the environment and their desire to help their communities through voluntary service. Through a variety of programs Earth Force, which serves 35,000 youth a year through 11 offices nationwide, helps young people discover and implement lasting solutions to environmental problems in their communities.

The In-House Counsel Committee's public service project is with Earth Force's GREEN program – the Global Rivers Environmental Education Network. This award-winning program developed nearly a decade ago at the University of Michigan matches middle and high school science classes with private sector sponsors to study and improve water quality in their community. A local watershed group also is involved in each GREEN project. The students and their teacher begin GREEN by doing a watershed assessment that includes physical, chemical and biological monitoring. Using this data and other resources, they identify a problem they would like to address. Students research the problem in a balanced fashion, review applicable legal or community considerations, and decide on their preferred solution. They then design and implement an action plan to address the problem, and conclude by reflecting on what they learned.



**Pesticides, Chemical Regulation,
and Right-to-Know
Committee Newsletter**

LIKE TO WRITE?

The Pesticides, Chemical Regulation, and Right-to-Know Committee welcomes the participation of members who are interested in preparing this Newsletter.

If you would like to lend a hand by writing, editing, identifying authors, or identifying issues, please contact the editor, Lynn Bergeson, at 202/557-3801 or lbergeson@lawbc.com.

BACK ISSUES

Back issues of this Newsletter can be viewed on the Pesticides, Chemical Regulation, and Right-to-Know Committee Web page at <http://www.abanet.org/environ/committees/pesticides/newsletter/archive.html>.

The private sector sponsors fund the students' water monitoring and testing equipment, which are kits pre-assembled by Earth Force. Professionals from the private sector sponsors are mentors to the students in the program, and serve as resources for their teachers by assisting in monitoring events, attending a class session, or being available by phone to give input to the class. There is no steadfast time commitment. Mentors can provide just a few hours of their time or more routine support to their host schools. The cost of sponsoring the necessary training, manuals, kits and support for a GREEN school in a city where GREEN infrastructure exists is \$5,000. Of course, this is often an excellent opportunity to meet other corporate leaders and to gain public recognition for your organization or firm. Bottom line, this is a "turn key" project – if we can raise the funds, Earth Force does the work to match the sponsors with schools and a watershed partner, and conducts the training!

By recruiting and pooling sponsors within a geographic area to reach the \$5,000 needed to move forward in a city with pre-existing GREEN activities, the In-House Counsel Committee already has started two projects to date. Our Indianapolis, Indiana, project is funded and supported by Eli Lilly, the law firm of Krieg DeVault, and the law firm of Harrison & Moberly. Our Baltimore, Maryland, project is funded and supported by the Section, Constellation Energy, Quality Environmental Solutions, and the law firm of McGuire Woods. We thank all of these dedicated entities for helping us kick this project off during the 2003 school year. The Indianapolis team has already been out in a waterbody with the students and their local nonprofit partner – Hoosier Riverwatch. Our Baltimore supporters recently had mentor training and will be out in the water in the spring.

We are hoping to start another project soon in one of the following cities: Lansing, Michigan;

Detroit, Michigan; Spring Hill, Tennessee; Shreveport, Louisiana; Houston, Texas; Austin, Texas; Philadelphia, Pennsylvania; Erie, Pennsylvania; Pittsburgh, Pennsylvania; Tampa/St. Pete, Florida; Charleston, South Carolina; Portland, Oregon; or Lordstown, Ohio. To begin GREEN efforts from scratch in a city beyond the aforementioned where GREEN activities already are ongoing, we need to raise \$25,000. We are hoping to accomplish this in Washington, D.C. to start. If your organization, firm or company is interested in committing all or part of the funds needed to start a project in one of these cities, please let me know at adunn@amsa-cleanwater.org.

What makes GREEN so exciting is that our efforts and time contributions show quick returns. The GREEN program generally is implemented from start to finish during a school year. As you can imagine, GREEN builds essential academic skills including critical thinking, teamwork, problem solving and decision-making; teaches students how to assess watershed health with the proper tools; and encourages youth to undertake projects to improve environmental quality based on their findings. Visit their Web site at <http://www.green.org> to learn more about GREEN. When we work together, young people and attorneys can improve their communities, learn and have fun at the same time! We hope you join our efforts!

**PESTICIDE, CHEMICAL
REGULATION AND RIGHT-TO-KNOW
COMMITTEE LIST SERVE**

environ-pesticides@mail.abanet.org

*Communicate with your
colleagues using the list serve!*

New from ABA Publishing and The Section of Environment, Energy, and Resources

Issues of Legal Ethics in the Practice of Environmental Law by Irma S. Russell

This new book is an essential guide for every environmental lawyer on representing industrial clients, government agencies, individuals, and public interest groups. It focuses primarily on the rules of ethics that raise significant concerns for the environmental practitioner. A proactive approach to ethics helps lawyers avoid problems by making reasoned decisions before ethical problems arise in urgent or complicated context. This book helps you anticipate and analyze these difficult ethics issues. This book also examines the American Bar Association's Model Rules of Professional Conduct (Model Rules), judicial decisions, formal and informal ABA Opinions, and opinions of state boards of professional responsibility. Contents Include:



- Regulation of Lawyers
- The Duty of Competence and the Lawyer's Duty of Diligence
- The Lawyer-Client Relationship
- Confidentiality
- Conflicts Concerns in Environmental Law
- Imputed Conflicts
- Duty of Candor
- The Lawyer's Duties to Non-Clients
- Alternative Dispute Resolution
- The Anti-Contact Rule
- Multi-Disciplinary Practice
- Multijurisdictional Practice
- Pro Bono Representations
- Lawyer Advertising
- Lawyer's Fees
- The Lawyer's Role in Working with Consultants
- The Lawyer Role in Working in Use of the Media
- Termination and Withdrawal from Representation

2003 6 x 9 480 pages

Product Code: 5350097

Price: Section of Environment, Energy, and Resources members \$64.95; Regular \$79.95

**TO ORDER ABA BOOKS, CALL 1-800-285-221 OR VISIT THE ABA PUBLISHING
WEB SITE AT WWW.ABABOOKS.ORG
QUESTIONS? E-MAIL: SERVICE@ABANET.ORG**