THE ENVIRONMENTAL COUNSELOR

SEPTEMBER 2012 | ISSUE 289

LETTER FROM THE EDITOR

Dear Subscribers,

This month's *The Environmental Counselor* covers a broad range of environmental law. Mark Duvall from Beveridge & Diamond, P.C. discusses EPA regulation of public health antimicrobials. Authors from Van Ness Feldman discuss a D.C. Circuit ruling on the Yucca Mountain licensing proceeding, *Aiken County, N.C. et al., v. NRC*, No. 11-1271. This month, authors from Marten Law discuss a petition for review being considered by the Supreme Court regarding CERCLA §§ 107 and 113, the law's cost recovery and contribution provisions. The updates section provides summaries of recent developments in environmental law. The coverage ranges from discussion of recent Clean Air Act rulings to the recent D.C. Circuit decision upholding government approval for a higher blend of corn ethanol into gasoline.

As always, we thank the authors for sharing their expertise in environmental law.

Very truly yours,
Michelle White-Savage
Attorney Editor

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EPA CONTINUES TO IMPROVE REGULATION OF PUBLIC HEALTH ANTIMICROBIALS**

By Mark Duvall

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The U.S. Environmental Protection Agency (EPA) has made a number of changes in recent years to improve regulation of antimicrobial pesticide products, particularly those related to public health. EPA's regulation of public health antimicrobials has long faced criticism, especially focused on the agency's efficacy testing and data review processes. In response, EPA has made significant efforts since 2009 to improve regulation of public health antimicrobials. The agency has worked to update testing guidelines, increase the rate of product testing, clarify enforcement protocols for ineffective products, and streamline regulatory processes. Manufacturers can now base tests of the efficacy of public health antimicrobials on the 810 Series test guidelines, finalized in 2012. Manufacturers are likely also relying on the Data Requirements rule that EPA proposed in 2008, although the draft final rule is still pending review by the Office of Management and Budget (OMB).

This client alert provides updates on EPA's regulation, testing, and enforcement activities related to public health antimicrobials since May 2009. It supplements Beveridge & Diamond's 2008 and 2009 antimicrobials client alerts on this topic.[1]

I. INTRODUCTION: ANTIMICROBIAL REGULATION THROUGH MAY 2009

A. OVERVIEW

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) includes antimicrobial products under its broad definition of pesticides. FIFRA requires that essentially all antimicrobial products be registered before they are sold in the United States. It establishes extensive testing and labeling requirements.[2]

Some antimicrobials are considered public health pesticides, defined in FIFRA as those "registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria, or other microorganisms. . . that pose a threat to public health."[3] By contrast, non-public health antimicrobials are not intended to protect humans from disease, but rather to protect inanimate objects from destructive bacterial growth.

Public health antimicrobial products are categorized as sterilizers, disinfectants, or sanitizers.[4] These products are regulated more stringently than other antimicrobials because serious consequences could arise from use of ineffective antimicrobials in medical settings. As a result, EPA must find that public health antimicrobials meet certain efficacy requirements to be approved for registration. No efficacy determination is required for non-public health antimicrobials.[5]

EPA's Office of Pesticide Programs (OPP) regulates antimicrobials and conducts the Antimicrobial Testing Program (ATP) to ensure that antimicrobials making public health claims meet EPA's efficacy standards. All registrants of antimicrobials must maintain efficacy data, but only applicants for products that make public health claims are required to submit their efficacy studies to EPA.[6] Registrants conduct their own testing and submit the results to OPP, which then determines whether to approve the product for sale. After a public health antimicrobial product is on the market, OPP conducts independent testing to ensure that the product meets efficacy standards.

B. CONTINUING CRITICISMS

Starting with a 1990 report by the Government Accountability Office (GAO), several government investigations over the last two decades have pointed out problems with OPP's regulation of public health antimicrobials.[7] The reports, issued by GAO as well as EPA's Office of Inspector General (OIG), repeatedly called on OPP to improve public health antimicrobial regulations. The reports critiqued the low rate of efficacy testing, high rate of product failures, inadequate enforcement against ineffective products, and lack of transparency. The reports also consistently noted that EPA's preferred efficacy testing method for public health antimicrobials, the AOAC Use-Dilution Method test (UDM), had long been criticized as unreliable. The validity of the UDM, at one time "the most widely used" efficacy testing method, has been debated for decades.[8]

Antimicrobial manufacturers were also concerned about the reliability of EPA's efficacy testing. If EPA's tests incorrectly identified a product as ineffective, manufacturers could wrongly be ordered to stop selling their product, or could face unjustified regulatory penalties. Manufacturers additionally criticized EPA's outdated antimicrobial regulations for failing to reflect the unique qualities of antimicrobials as compared to other types of pesticides.

C. 2008 PROPOSED DATA REQUIREMENTS RULE

In 1996, Congress directed EPA to address the problems raised in the GAO and OIG reports. The Food Quality Protection Act of 1996 (FQPA) added subsection (h) to FIFRA Section 3, requiring EPA to propose "regulations to accelerate and improve the review of antimicrobial pesticide products" within one year.[9] Three years later, EPA proposed registration requirements and other regulatory changes for antimicrobials.[10] Among other changes, the 1999 proposal would have established 12 new use patterns specific to antimicrobials. The use patterns were intended to address the unique character of antimicrobial pesticides and to assist applicants in determining which data requirements applied to their products.

In the preamble to the 1999 proposed rule, EPA wrote that it "agree[d] wholeheartedly that measures to strengthen the Agency's oversight of antimicrobial efficacy. . . are desirable." However, in 2001, EPA finalized only the portions of the proposed rule that did not relate to antimicrobials, noting that the nonantimicrobial provisions were "uncontroversial."[11] The portions of the proposed rule relating to antimicrobials remained unfinalized and were officially withdrawn in 2011.[12]

In 2008, EPA again issued proposed revisions to the antimicrobial Data Requirements rule.[13] In developing the 2008 proposal, EPA considered comments received on the 1999 proposal. Some elements of the proposal remained the same. For example, the 2008 proposal included identical definitions for various types of antimicrobials, identical criteria upon which EPA should consider whether a product made a public health claim, and the same twelve new use patterns. The 2008 proposed Data Requirements rule also included several changes from the 1999 proposal. Among other changes, the proposed rule divided the twelve new use patterns into either "high" or "low" environmental exposure categories.

The 2008 proposed rule met with some industry criticism. Some commenters said the proposal failed to sufficiently clarify the data requirements and did not appropriately address the uniqueness of antimicrobial pesticides. Some groups objected to EPA's proposed definitions of "public health claims," "disinfectants," and "sanitizers," arguing that these definitions inappropriately effected policy change via rulemaking.[14]

II. JUNE 2009-PRESENT: ANTIMICROBIAL REGULATION DEVELOPMENTS

A. 2010 EPA OIG REPORT

In 2010, OIG issued a new report evaluating ATP's efficacy testing processes for public health antimicrobials. The report, *EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products*, reiterated some of the same criticisms contained in the previous GAO and OIG reports. In particular, OIG found that ATP's testing rate remained low: at the time of the investigation, 40% of registered public health antimicrobial products had not undergone efficacy testing. For the 60% of products that had undergone testing, the report observed that ATP still reported a "consistently high failure rate."[15]

OIG also found that the test sample submission process did not adequately lay the groundwork for enforcement actions. The submission process was based on voluntary submissions from manufacturers, and the voluntary submissions frequently did not establish the chain of custody required to pursue enforcement proceedings. Enforcement practices were additionally weakened by inconsistent policies across the different EPA regions. OIG further noted that ATP's communication strategy did not effectively inform public health antimicrobial purchasers, like hospitals, about test results or enforcement actions.

In response to the report, EPA accepted most of OIG's findings and agreed that the ATP should be redesigned. EPA stressed that it does communicate with medical institutions, and emphasized its belief that the majority of public health antimicrobials in actual use have been tested. EPA further noted that OPP has put in place a number of measures geared towards "developing a more streamlined and effective program."[16] These measures include revising the Standard Operating Procedures for sample collection, establishing a database to better track products, and improving chain of custody procedures to better facilitate enforcement.

B. EFFICACY TEST GUIDELINE SERIES

In 2012, EPA finalized the Series 810 Prod-

uct Performance Test Guidelines for Public Health Uses of Antimicrobial Agents. The guidelines provide detailed recommendations for efficacy testing procedures for different types of public health antimicrobials. The first slate of Series 810 efficacy testing guidelines, finalized in March 2012, addresses agents that act as sterilants, disinfectants, and sanitizers on hard and inanimate surfaces.[17] The second set of guidelines, finalized in June 2012, addresses disinfectants and sanitizers intended for use in water, or on fabrics and textiles, and air sanitizers.[18]

The guidelines do not eliminate the controversial UDM test, although they note that EPA is considering adopting quantitative test methods "as a possible replacement for current qualitative methods."[19] Qualitative methods are those that categorize results in qualitative categories, such as "Growth" or "No Growth." The UDM is a qualitative test. Ceasing to recommend qualitative methods would therefore mean eliminating all application of the UDM.

The testing guidelines that address disinfectants for use on hard surfaces recommend the UDM as an appropriate test for water-soluble powders and liquids, including those used in healthcare environments. In most cases where the UDM is recommended for this type of antimicrobial, the guidance also lists an alternative recommended option (such as the AOAC Hard Surface Carrier Test).[20]

The testing guidelines for disinfectants and sanitizers used on textiles and fabrics[21] and in water[22] also recommend the UDM. They do not list alternative recommended options.

The testing guidelines addressing sterilants[23] and sanitizers[24] for use on hard surfaces and the guidelines for air sanitizers[25] do not recommend the UDM.

C. TESTING PROGRAM IMPROVEMENTS

In response to criticisms that OPP lacked transparency, ATP now releases its efficacy testing records for public health antimicrobials. Two years after the 2010 OIG report, the testing statistics indicate that ATP has significantly increased its testing rate. As of May 2012, ATP had conducted efficacy testing on around 70% of all registered public health antimicrobial products. In comparison, at the time of OIG's 2010 investigation, ATP had tested 60% of products on the market.

Although ATP is conducting more efficacy testing of public health antimicrobials overall, a significant number of tested products still fail to meet efficacy standards. As of May 2012, around 30% of tested products did not meet efficacy standards.

Based on the number of untested products and the number of products that failed testing, as of May 2012, ATP had confirmed the efficacy of 50% of all public health antimicrobials on the market.[26]

In July 2010, ATP underwent a management effectiveness review, known as a "Lean Review," to identify ways to improve its internal processes. In February 2011, ATP reported progress on some of the goals identified by the Lean Review, such as reducing the time required to conduct testing, and encouraging consistency and clarity between regional offices' sample collection procedures.[27]

D. ENFORCEMENT

In December 2009, EPA updated the FIFRA Enforcement Response Policy (ERP), the guide used by EPA's Office of Enforcement and Compliance Assurance (OECA) to determine appropriate enforcement responses for FIFRA violations.[28] EPA says that adoption of the new ERP has successfully addressed the enforcement inconsistencies identified by the 2010 OIG report, because those inconsistencies occurred under the old ERP. The 2009 ERP was scheduled for review in December 2011, but in-

formation on that review is not yet publicly available.[29]

According to the May 2012 ATP testing statistics, 23% of total registered public health antimicrobial products were subject to "agency action" due to efficacy test failure. The testing statistics report does not state the type of agency action being pursued against specific products. As defined by the testing statistics report, "agency action" could include a range of activities, from requiring additional testing to initiating enforcement action.[30]

Most likely, the agency actions indicated by the testing statistics report are not enforcement actions. Overall, EPA pursues relatively few enforcement actions based on efficacy test failures. Between 2007 and 2010, EPA launched eleven enforcement actions against public health antimicrobials that failed efficacy testing. Of those, 10 were initiated between 2007 and 2009, one was initiated in 2010, and none has been initiated since.[31] Penalties ranged from $2,000 to $552,400.[32]

Most failed products are therefore probably subject to regulatory actions, such as requiring additional testing or cancelation of the registration. Manufacturers may also participate in settlements outside of the scope of enforcement proceedings.

To address the chain of custody issue raised in the 2010 OIG report, OPP has worked to improve its handling of samples to facilitate enforcement.[33] In September 2010, OECA issued a revised ATP Sample Collection Protocol and issued additional guidance on the collection of products in the marketplace. EPA also began recommending that each regional office appoint an ATP coordinator to assist inspectors in locating samples.[34]

E. PENDING OMB REVIEW OF DATA REQUIREMENTS RULE

In October 2011, 15 years after FQPA directed EPA to issue an antimicrobials rulemaking, EPA forwarded the draft final Data Requirements rule to OMB for review. EPA's latest Regulatory Agenda predicted that the final rule would be published in February 2012, but OMB's review has delayed that date.[35] OMB's delay in reviewing the rule may be part of a general slowdown in regulatory developments in anticipation of the 2012 presidential election.

III. CURRENT STATUS

Although OMB review of the 2008 proposed Data Requirements rule is still pending, the rule is apparently followed in practice. The Pesticide Registration Manual, EPA's resource for companies seeking to register pesticides, encourages companies to rely on the proposed rule. The manual notes that although the proposed rule "has not been promulgated and is not in effect, EPA believes that it contains useful information that registrants may wish to consult in trying to determine what data may be required for particular use patterns of antimicrobial pesticides."[36]

Within the next year, the ATP Lean Review is expected to issue recommendations on the future structure of ATP. EPA will likely continue to revise its registration, testing, enforcement, and communication procedures to increase the efficiency and efficacy of antimicrobials regulation.

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ENDNOTES:

[1]See Beveridge & Diamond, P.C. Client Alert, "EPA Proposes New Data Requirements for Antimicrobial Pesticide Products" (Nov. 10, 2008), http://www.bdlaw.com/news-409.html; Beveridge & Diamond, P.C. Client Alert, "Proving Antimicrobial Efficacy—A Continuing Controversy" (July 9, 2009), http://www.bdlaw.com/news-622.html.

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

[3]FIFRA § 3(nn), 7 U.S.C.A. § 136(nn).

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

[5]40 C.F.R. § 161.640(a).

[6]40 C.F.R. § 161.640(b)(1).

[7]See, e.g., General Accounting Office, GAO/RCED-90-139, Disinfectants: EPA Lacks Assurance That They Work (1990), http://www.gao.gov/products/RCED-90-139 ["GAO Report"]; U.S. EPA OIG, EPA Did Not Properly Process a Hospital Disinfectant and Sanitizer Registration, Public Liaison Report No. 2007-P-00018, at 12, (Mar. 29, 2007), http://www.epa.gov/oig/reports/2007/20070329-2007-P-00018.pdf.

[8]GAO Report.

[9]Pub. L. No. 104-170, FQPA § 224(h), 110 Stat. 1489 (1996).

[10]64 Fed. Reg. 50672 (Sept. 17, 1999).

[11]66 Fed. Reg. 64759 (Dec. 14, 2001).

[12]OMB, Registration Requirements for Antimicrobial Pesticide Products, RIN 2070-AD14, http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201110&RIN=2070-AD14.

[13]73 Fed. Reg. 59382 (Oct. 8, 2008).

[14]See Beveridge & Diamond, P.C. Client Alert, "EPA Proposes New Data Requirements for Antimicrobial Pesticide Products" (Nov. 10, 2008), http://www.bdlaw.com/news-409.html.

[15]EPA OIG, 11-P-0029, EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products (Dec. 15, 2010), www.epa.gov/oig/reports/201½0101215-11-P-0029.pdf.

[16]EPA, Comments on OIG's Draft Evaluation Report "EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products" (Oct. 26, 2010), www.epa.gov/oig/reports/201½0101215-11-P-0029.pdf (see Appendix A) ["EPA OIG Response 1"].

[17]77 Fed. Reg. 15750 (Mar. 16, 2012).

[18]77 Fed. Reg. 38280 (June 27, 2012).

[19]EPA, OCSPP 810.2000: General Considerations for Public Health Uses of Antimicrobial Agents (Mar. 12, 2012), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0150-0012.

[20]EPA, OCSPP 810.2200: Disinfectants for Use on Hard Surfaces-Efficacy Data Recommendations (Mar. 12, 2012), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0150-0014.

[21]EPA, OCSPP 810.2400: Disinfectants and Sanitizers for Use in Water - Efficacy Data Recommendations (May 30, 2012), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0150-0016.

[22]EPA, OCSPP 810.2600: Disinfectants and Sanitizers for Use on Fabrics and Textiles - Efficacy Data Recommendations (May 30, 2012), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0150-0018.

[23]EPA, OCSPP 810.2100: Sterilants-Efficacy Data Recommendations (Mar. 12, 2012), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0150-0013.

[24]EPA, OCSPP 810.2300: Sanitizers for Use on Hard Surfaces-Efficacy Data Recommendations (Mar. 12, 2012), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0150-0015.

[25]EPA, OCSPP 810.2500: Air Sanitizers-Efficacy Data Recommendations (Mar. 12, 2012), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0150-0017.

[26]EPA, Antimicrobial Testing Program (ATP) Status as of May 9, 2012, http://www.epa.gov/oppad001/atp-summary-05-09-12.pdf ["ATP Status Report"].

[27]EPA, EPA Office of Pesticide Programs Antimicrobial Testing Program Lean Event Case Study, http://www.epa.gov/lean/government/epa-initiatives/opp-casestudy.htm. EPA's testing statistics do not note whether the products were tested using the UDM.

[28]EPA, FIFRA Enforcement Response Policy (Dec. 2009), http://www.epa.gov/compliance/resources/policies/civil/fifra/fifra-erp1209.pdf.

[29]EPA, Comments on OIG's Draft Evaluation Report "EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products" (Feb. 25, 2011), http://www.epa.gov/oig/reports/2011/11-P-0029%20__Agency__Response.pdf ["EPA OIG Response 2"].

[30]ATP Status Report.

[31]EPA, Admin. Enforcement Docket, http://yosemite.epa.gov/oa/rhc/epaadmin.nsf (last updated June 29, 2012).

[32]See, e.g., Press release, EPA Reaches Settlement with Nation's Largest Manufacturer of Hospital Disinfectants; Company Agrees to Pay $550,000 in Penalties, July 31, 2009, http://yosemite.epa.gov/opa/admpress.nsf/0/07D14570FB49E137852576040062CD86.

[33]EPA OIG Response 1.

[34]EPA OIG Response 2.

[35]OMB, Pending EO 12866 Regulatory Review, http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201110&RIN=2070-AD30 (last visited June 21, 2012).

[36]EPA, Pesticide Registration Manual, Chapter 4: Additional Considerations for Antimicrobial Products (Aug. 2011), http://www.epa.gov/pesticides/bluebook/chapter4.html.

SUPREME COURT ASKED TO RESOLVE INTERPLAY BETWEEN CERCLA COST RECOVERY AND CONTRIBUTION PROVISIONS**

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