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MEMORANDUM

Via E-Mail

DATE: December 9, 2009

TO: Firm Clients and Friends

FROM: Bergeson & Campbell, P.C.

RE: EPA Announces Development of Voluntary Pilot Programs for Antimicrobial Pesticide Products

Today the U.S. Environmental Protection Agency (EPA) Office of Pesticide Programs (OPP) announced the development of two voluntary pilot programs for antimicrobial pesticide products. Working collaboratively with the Pesticide Program Dialogue Committee (PPDC), OPP explored the different types of label statements and logos for antimicrobial pesticide product labels. OPP developed the Factual Label Statement Pilot Program and the OPP-Design for the Environment (DfE) Logo Pilot Program. In today's *Federal Register* notice, OPP states that no antimicrobial registrant is required to participate in the pilot programs, as they are both voluntary pilots.

Factual Label Statement Pilot Program

According to the notice, OPP is increasingly reviewing pesticide labels that contain purportedly factual statements implying safety or environmental preferability of products. In each case, OPP must determine that the statements are not false or misleading before approving the label in accordance with Sections 2(q)(1)(A) and 3(c)(5)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). OPP states that this determination "is rarely easy in the absence of any data on consumer perceptions of such claims." To increase the efficiency of such determinations, OPP and the PPDC Workgroup on Factual Statements attempted to identify types of factual claims that would generally not be misleading and thus could be easily reviewed and approved by OPP. At this time, OPP states, it has determined that only a subset of the initially considered factual statements would be generally acceptable on antimicrobial pesticide labels.



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The Factual Label Statement Pilot Program will permit the addition of the following factual statements to antimicrobial pesticide product labels when the terms are met by registrants:

- ***Dyes and/or fragrance free statements*** -- OPP will permit for the purposes and duration of the pilot program the following label statements to be placed on qualifying antimicrobial pesticide products: “Dye-free,” “Fragrance-free,” and “Dye and fragrance free.” Registrants applying for this pilot program must submit as part of their application the current Confidential Statement of Formula (CSF) and a draft label with the new statements. OPP will examine the CSF to verify the dye/fragrance free claim prior to granting use of the label. Upon initial pre-acceptance of the statement(s) by OPP, a final printed label must be submitted before the labeling is stamped acceptable.

- ***Corporate commitment statements*** -- OPP will permit for the purposes and duration of the pilot program the following label statement on qualifying antimicrobial pesticide products: “For technical assistance or information on [INSERT THE NAME OF THE COMPANY] environmental/sustainability initiatives, go to [INSERT COMPANY WEBSITE].” Registrants applying for this pilot program must submit as part of their application a link to their company’s website and their product’s draft label with the new statement. Upon initial pre-acceptance of the statement(s) by OPP, a final printed label must be submitted before the labeling is stamped acceptable.

In addition, today’s notice states that EPA has decided to allow the addition of information concerning product packaging of an antimicrobial pesticide product, such as the recycled content of the product’s packaging, in lieu of a pilot. EPA examined OPP’s existing Pesticide Registration Notice (PRN) 98-10, “Notifications, Non-Notifications and Minor Formulation Amendments,” available at http://www.epa.gov/PR_Notices/pr98-10.pdf. The PRN provides the following guidance regarding recycled content:

A statement about the recycled content of pesticide packaging itself may be made in accordance with guidance from the Federal Trade Commission.



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According to today's notice, EPA concluded that the PRN sufficiently provided for label statements about product packaging, and therefore recycled content of product packaging additions may be made through the notification process at any time.

To be considered for the Factual Label Statement Pilot Program, applicants must adhere to all the terms of the pilot, submit all of the applicable forms and fees (if necessary), and follow the pilot's mailing/delivery instructions. The notice states that detailed instructions on applying for the pilot are available at <http://www.epa.gov/pesticides>. If EPA determines, at any time during the pilot, that a company is making violative claims either on the product label or associated websites, the company will be subject to enforcement action under FIFRA and other applicable laws. EPA may exclude any company deemed to be in violation from further participation in either of the pilots.

OPP will start accepting product label amendment applications for the Factual Label Statement Pilot Program on **January 25, 2010**. If OPP decides not to allow use of approved factual statements at the end of the pilot, then the last day that pesticide products participating in this pilot can be released for shipment is **May 3, 2013**.

OPP-DfE Logo Pilot Program

According to today's notice, OPP is working with EPA's DfE program in the Office of Pollution Prevention and Toxics (OPPT) "to empower consumers to make informed choices when purchasing antimicrobial pesticide products, and encourage registrants to develop pesticide formulations that are at the lower end of the toxicity spectrum." The OPP-DfE Logo Pilot Program is targeted towards antimicrobial pesticide products that are either acute toxicity categories 3 or 4. In general, OPP states, antimicrobial pesticide products with the following characteristics would likely not qualify:

- Are classified as acute toxicity category 1 or 2;
- Have known, likely, or suggestive carcinogens;
- Have known developmental, reproductive, mutagenic, or neurotoxicity issues;
- Have significant, outstanding data issues for the active ingredient and/or product; or
- The label requires use of personal protective equipment.



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EPA states that additional criteria and details on the pilot are available at <http://www.epa.gov/pesticides>.

Participation in the pilot will require both a review under the DfE program, as well as OPP's review of the registration application. Registrants must first submit their products to the DfE program for review, along with any data necessary to prove that the product is eligible for recognition under their criteria. Once the DfE program determines that the product meets their program's criteria, the registrant must then submit to OPP their amendment request, including their draft label with the OPP-DfE logo. OPP states that it will not accept applications that have not completed the DfE review. The acceptable label statement accompanying the OPP-DfE logo is: "For further information concerning the DfE for Pesticides Program, go to <http://www.epa.gov/pesticides>." According to the notice, OPP is creating this OPP-DfE website to reduce any potential confusion by consumers or registrants between the OPP-DfE program and the existing DfE program for non-pesticide products.

Participation in the pilot requires the submission of a complete application for a Pesticide Registration Improvement Act (PRIA) regulatory application and, therefore, is subject to the applicable fees under PRIA. OPP will complete its review of the amendment according to the PRIA timeframe. The DfE program will start accepting applications for the OPP-DfE Logo Pilot on **December 9, 2009**. OPP will start accepting product amendment applications starting on **May 3, 2010**. This pilot ends on **May 3, 2013**, and the last day that pesticide products participating in this pilot can be released for shipment is **May 3, 2013**.

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We hope this information is helpful. As always, please call if you have any questions.