



**US Environmental Protection Agency
Office of Pesticide Programs**

**Pesticide Registration (PR) Notice 2009-1
Establishment of Antimicrobial Exposure
Assessment Task Force II**

September 30, 2009

Pesticide Registration (PR) Notice 2009-8/17/09

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS AND REGISTRANTS OF ANTIMICROBIAL PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registrations and Re-registrations of Antimicrobial Pesticides.

SUBJECT: Establishment of Antimicrobial Exposure Assessment Task Force II

I. Introduction

This PR Notice announces the establishment of the Antimicrobial Exposure Assessment Task Force II (AEATF II), an industry-wide task force to jointly develop mixer, loader, applicator (herein after "handler"), and post-application exposure data for antimicrobial pesticides used in commercial, institutional, occupational, and consumer settings. This Notice discusses why these data are being developed and how registrants may participate in the AEATF II's development of these data. Any applicant or registrant may choose among other ways of supplying such data as it becomes required, including generation and submission of its own data. This Notice identifies contacts within the Environmental Protection Agency (EPA) and AEATF II for persons wanting further information.

This PR Notice is issued by the Agency for the sole purpose of informing antimicrobial pesticide registrants and applicants of the establishment of the AEATF II. It is not intended to define or restrict the terms of or subsequent amendments to the joint data development agreement and its operation, nor is it intended to compel any registrant or applicant to participate or rely upon the Task Force's data generation and submission efforts.

II. Background

Since the 1980s, EPA has required pesticide exposure data in order to assess the occupational and consumer risks of both new and existing pesticides. Historically, an applicant or registrant would conduct active ingredient-specific exposure studies for workers or consumers mixing, loading, and applying (handling) pesticides, and for individuals re-entering treated areas, in order to provide information to the Agency. As EPA learned from these early studies and as the scientific community studied occupational and consumer exposure data, it became widely accepted that handler (mixer, loader and applicator) exposure to pesticides is not a function of the active ingredient used, but rather is dependent on other factors, such as the activity performed, the formulation type, personal

protective equipment and engineering controls used, and the amount of pesticides handled.

In the early 1990s, industry and government cooperated in building the Pesticide Handlers Exposure Database (PHED), as well as the Chemical Manufacturers Association (CMA) exposure database specifically for antimicrobials, to support assessments of handler exposure to pesticides. In the case of PHED, companies contributed their existing exposure data for the common benefit of all registrants, waiving their rights to data compensation. However, the CMA exposure data were provided to the EPA as a proprietary data set. Regulatory agencies have used both PHED and CMA data since their development and applicants and registrants have cited these databases to satisfy many handler exposure data requirements.

III. Need for Additional Exposure Data

Since the development of PHED and CMA exposure data, it has become clear that some antimicrobial handler exposure scenarios may not be adequately covered in these databases. Some existing data may not fully represent current exposure patterns. However, these data still represent the best available information for assessing handler exposures. In January 2007, EPA convened a FIFRA Scientific Advisory Panel (SAP) to address the need for a new generation of handler exposure data and to recommend methods for generating them. The SAP confirmed the need for new handler exposure studies and generally supported the methods proposed for conducting these studies http://www.epa.gov/scipoly/sap/meetings/2007/010907_mtg.htm.

IV. Establishment of the Antimicrobial Exposure Assessment Task Force II

The AEATF II was formed in November 2004 to develop additional data to better represent actual exposure levels for a wider range of antimicrobial pesticide handler activities. The mission of the AEATF II is to share technical and financial resources in the design, evaluation, and development of a proprietary antimicrobial handler exposure database for use in regulatory risk assessments.

The AEATF II over the next four to six years plans to conduct additional field studies that would be intended to meet current scientific and ethical standards. The final database will be proprietary to AEATF II members, and AEATF II will retain all rights to data compensation. Accordingly, in the future, when AEATF II studies are chosen to be cited by applicants or registrants to satisfy FIFRA data requirements, the applicants or registrants must either be members of AEATF II or offer to pay compensation to the AEATF II for the use of the data.

The AEATF II exposure monitoring data development program is discussed in detail in a "Governing Document" presented to the Human Studies Review Board

(HSRB) in 2008. (<http://www.epa.gov/osa/hsrb/apr-9-10-2008-public-meeting.htm>).

The primary objective of the AEATF II is to generate handler exposure monitoring studies to estimate/characterize exposure distributions for a multitude of occupational/industrial and consumer exposure scenarios involving antimicrobial products. The data from these studies would be intended to fill gaps in the current antimicrobial exposure dataset and allow for better estimations of potential dermal and inhalation occupational risks to workers and consumers handling products containing antimicrobial agents. The study results deemed to be acceptable will be placed into a computer software database (i.e., the Biocide Handlers Exposure Database or BHED™) allowing the data to the extent they are found to be acceptable by the Agency to be used generically for risk assessments of all antimicrobial pesticide products. The AEATF II intends to exercise the rights associated with submission of data under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) in connection with Biocide Handler Exposure Database (BHED™). The database will be available to both AEATF II members (and others who qualify for access) and regulatory agencies for registration, re-evaluation, and registration review purposes.

The AEATF II study program has been designed to cover the most common types of occupational and residential handling scenarios involving antimicrobials. Initially, EPA identified application methods and use scenarios based on a review of antimicrobial product labels and/or Agency areas of interest, in conjunction with 12 "Use Site Categories" that EPA has used historically to delineate antimicrobial use sites. Some application methods have been combined in practice. The EPA "Use Site" categories and the application methods/use scenarios (each representing one or more exposure monitoring studies) currently included in the AEATF II study program are as follows:

EPA Use Site Categories:

1. Agricultural Premises and Equipment
2. Food Handling/Storage Establishments Premises/Equipment
3. Commercial, Institutional & Industrial Premises/Equipment
4. Residential and Public Access Premises
5. Medical Premises and Equipment
6. Human Drinking Water Systems
7. Industrial Process Water Systems
8. Material Preservatives
9. Antifoulant Coatings
10. Wood Preservatives
11. Swimming Pools
12. Aquatic Areas

Application Methods/Use Scenarios (AEATF II use scenario-specific studies):

1. Aerosol Spray
- 2 - 5. High to Low Pressure Spray (4 studies)
6. Pour Liquid
7. Pump Liquid
8. Pour Solid
8. Place Solid
10. Mop
11. Wipe
12. Fog
13. Brush/Roll
14. Airless Spray
15. Immerse/Dip/Soak
16. Pressure Treat
17. Metalworking Fluid

Although the main focus of the AEATF II is expected to be handler exposure data, post-application scenarios are also under discussion, with the possibility of developing test protocols, and conducting two studies – one to evaluate exposure (e.g., transferable residue measurements) of antimicrobials on soft surfaces (such as carpet) and one to evaluate exposure to antimicrobials on hard surfaces (such as countertops or wood decking).

All Task Force human subject monitoring studies will be conducted using standard industrial hygiene passive dosimetry techniques, consisting of both dermal and inhalation monitoring. All Task Force studies will be conducted according to current EPA Office of Pesticide Programs' Harmonized Test Guidelines—Series 875 Occupational and Residential Exposure Test Guidelines (Series 875 A and B for handler and re-entry, respectively) and conducted under Good Laboratory Practice standards per 40 CFR Part 160. All monitoring study protocols and studies will be reviewed by EPA and the HSRB for compliance with all applicable provisions of EPA's regulations providing for the protection of human subjects of research, 40 CFR Part 26. The Task Force has indicated that it is designing study protocols intended to allow study results to be broadly acceptable to both North American and European regulatory authorities.

While the AEATF II has reported that it has tried to include scenarios representing the majority of antimicrobial use patterns, certain uses, unique application methods, or other factors may lead EPA to require handler (and post-application) exposure data that may not be available through the AEATF II.

V. Agency Use of AEATF II Data

EPA considers all relevant, available information about handler exposure in its exposure assessments for new or existing registrations. The data generated by the AEATF II are expected to provide EPA with substantially better information than the Agency now has for assessing handler exposure for a number of reasons. The newer studies are expected to better reflect larger numbers of workers and use methods that provide more accurate estimates of exposure (e.g., whole body dosimeters vs. patches). They also are expected to have better field recovery values. EPA plans to use the AEATF II data, if they are deemed adequate and appropriate once they are received and reviewed in terms of current scientific and ethical standards, to assess a wide range of handler scenarios.

Should an applicant or registrant choose to seek to rely on AEATF II data to support a registration application or the continued registration of a product, the applicant or registrant must either be a member of AEATF II and therefore entitled to use AEATF II data, or the applicant or registrant must comply with the data compensation provisions of sections 3(c)(1)(F), 3(c)(2)(B), and 3(g)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

VI. Current Members

A list of current members of the Task Force can be obtained by contacting the AEATF II directly.

VII. How to Obtain Additional Information about the AEATF II

Those desiring further information on the AEATF may contact the following person:

Hasmukh Shah
Manager, Antimicrobial Exposure Assessment Task Force II
American Chemistry Council
1300 Wilson Blvd
Arlington, VA 22209
Email: has_shah@americanchemistry.com
Phone: (703) 741-5637

VIII. Scope of This Notice

This PR Notice provides general guidance to EPA and to pesticide registrants and applicants, and the public. This guidance is not binding on either EPA or any outside parties, and the EPA may depart from the guidance where circumstances warrant and without prior notice. In their submissions, registrants and applicants may propose alternatives to the recommendations described in this notice, and the Agency

will assess them for appropriateness on a case-by-case basis and will respond in writing.

IX. Agency Contact

For questions or further information regarding this PR Notice, please contact:

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Signed: Debra Edwards Dated: 9/30/09

Debra Edwards, Ph.D., Director

Office of Pesticide Programs