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Item: 6131

Pesticide Registration (PR) Notice 2000-7

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

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

SUBJECT: The Non-Dietary Exposure Task Force

I. Introduction

This PR Notice announces an industry-wide task force to jointly develop residential indoor exposure data for pesticides containing one or more of the active ingredients synthetic pyrethroids, pyrethrum and synergists. This Notice explains why these data are being developed and how registrants may wish to participate in the development of these data by joining the Task Force. The Notice identifies an Environmental Protection Agency (EPA) and a Task Force contact for persons wanting further information.

II. The Federal Food, Drug, and Cosmetic Act (FFDCA) Requirement To Consider Available Exposure Information

The FFDCA requires EPA to consider available information concerning dietary and non-dietary routes of exposure when assessing a pesticide-s residue risks, especially to children. The Non-Dietary Exposure Task Force (ATask Force or ANDETF) was formed in July, 1997 to jointly develop residential indoor exposure data on pesticides containing synthetic pyrethroids, pyrethrum and synergists (through the representative synergist piperonyl butoxide) as active ingredients (Athe active ingredients). NDETF data, once developed, will be one form of available data that may inform decisions on pesticide residue tolerances as well as registration and reregistration activities for pyrethroids as well as other active ingredients to which the data may relate. Applicants and registrants seeking to rely on NDETF to satisfy any applicable EPA data submission requirements must comply with the applicable provisions of section 3(c)(1)(F) and 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regarding data compensation.

III. Residential Indoor Exposure Data

The NDETF, in consultation with scientists from EPA, the California Environmental Protection Agency (Cal-EPA), Canada's Pest Management Regulatory Agency (PMRA) and the Health Safety Executive (UK), has designed, through pilot studies, a program to assess the transferability

of the active ingredients following different types of applications. The studies will utilize standardized application methods, validated analytical methods and measure transferability and photodegredation on carpet and vinyl flooring surfaces. While the class of active ingredients referred to as synthetic pyrethroids includes a spectrum of substances, the NDETF intends to test a range of synthetic pyrethroids that could be representative of the class in addition to the Task Forces testing of pyrethrum and piperonyl butoxide.

EPA will consider relevant, available information regarding dietary and non-dietary routes of exposure as part of a registration application or amendment, a reregistration eligibility determination or a pesticide residue tolerance assessment. EPA has relatively few studies assessing indoor exposure to pesticides. In the absence of studies that can be used to accurately assess such exposures, EPA will use appropriate estimates or other modeling to assess potential exposures. The development of indoor exposure studies would likely provide EPA with a more accurate tool for assessing these exposures. In some instances, EPA may in the future determine that development of indoor exposure data is in fact necessary to support applications, existing registrations, or tolerance assessments (and reassessments). Pesticide registrants and applicants wishing to develop such data may wish to participate in the NDETF.

Any pesticide registrants or applicants who believe they may need to satisfy indoor residential exposure requirements in the future or believe such data may better inform EPA=s assessments may wish to presently join the Task Force. Should EPA impose a requirement to submit or cite indoor residential exposure data or should an applicant or registrant otherwise rely on NDETF data [to support or maintain registration], a registrant or applicant electing to participate in NDETF=s study, must at the appropriate time, inform the agency of its election of this option and provide evidence of its membership in the Task Force or evidence that it has complied with any applicable data compensation requirements. In accordance with FIFRA, in the event that the NDETF and a non-member who cites to NDETF=s data to satisfy a data submission obligation are unable to reach agreement, the terms and amount of compensation shall, upon the request of either party, be determined by binding arbitration, as provided in sections 3(c)(1)(F) and 3(c)(2)(B) of FIFRA.

IV. Current Members

Current Members of the Task Force are Aventis Environmental Science (formerly AgrEvo Environmental Health), Botanical Resources Australia, Ltd., Endura S.p.a., McLaughlin Gormley King Company, Prentiss Incorporated, Pyrethrum Board of Kenya, S.C. Johnson & Son, Inc., and Takasago International.

V. Joining the NDETF

The Agency is not a participant in the NDETF but is available as the Agency deems appropriate to provide guidance and assistance relating to the development of the data. As noted, the Agency and other regulatory authorities have provided input to the NDETF. The following information was supplied to EPA by the NDETF for the benefit of registrants and applicants of the active ingredients interested in joining the Task Force: The NDETF is organized under a FIFRA joint

data development agreement with certain common developmental costs shared equally among all registrants and certain costs shared according to the number active ingredients registered by the registrant. Membership is available for a period of six months from the date of issuance of this PR Notice upon payment of an appropriate share of prior member assessments, adjusted for interest. Thereafter, membership is available by paying an appropriate share of all assessments, interests and certain late fees. Each participating company has the right to appoint one representative to the Steering Committee and the Technical Committee of the NDETF. Those desiring further information on the Task Force may contact the following:

Paul Keane, Chairman, Steering Committee, Non-Dietary Exposure Task Force, 47 West Division Street, Suite 389, Chicago, IL 60610.

Phone: (312) 664-4781 Fax: (312) 664-0728 Email: Pkeane2100@aol.com

Tom Osimitz, Ph.D., Chairman, Technical Committee, Non-Dietary Exposure Task Force, S.C. Johnson & Son, Inc., 1525 Howe Street, M.S. 122, Racine, WI 53403.

Phone: (414) 260-2669 Fax: (414) 260-0186 Email: tgosimit@scj.com

VI. What the NDETF Will Do

The work product expected to be developed and submitted by and through the NDETF will include but is not limited to the following study reports for the active ingredients that are the subject of the program:

- Method Development for Measurement of Transferable Residues from Vinyl Flooring and Carpet Using the Indoor Roller.
- Method Development for Measurement of Transferable from Vinyl Flooring and Carpet Using the Drag Block/Drag Winch.
- Measurement of Residue Transfer of Active Ingredients From Treated Carpet and Vinyl to Human Hands.
- Fate of Active Ingredients in a Household Spray Formulation Exposed to Various Indoor and Outdoor Lighting Conditions.
- Post-Application Deposition Measurements for Active Ingredients Following Use of a Total Release Indoor Fogger.

It is possible that the program will include additional study reports and it is possible that certain use patterns, uncommon formulations, or other situations may arise for which EPA might require

separate indoor residential exposure data from an applicant or a registrant that would not be available through the work performed by the Task Force.

This PR Notice is issued by the Agency for the sole purpose of informing pesticide registrants and applicants of the formation of the NDETF. It is not intended to define or restrict the terms of or subsequent amendments to the joint data development agreement and its operation.

VII. For Further Information

For questions or further information regarding the NDETF, please contact Alan Dixon at (703) 305-7237.

Signed: Joseph J. Merenda,

For Marcia E. Mulkey, Director Office of Pesticide Programs

Dated: August 4, 2000