



US Environmental Protection Agency Office of Pesticide Programs

Pesticide Registration (PR) Notice 2011-1 Residential Exposure Joint Venture

January 3, 2011

Pesticide Registration (PR) Notice
2011-1

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

ATTENTION: Persons Responsible for Federal Registrations and Re-evaluations (Re-registration and Registration Review) of Pesticides.

SUBJECT: Residential Exposure Joint Venture

I. Introduction

This PR Notice is to advise registrants of an industry-wide joint venture, titled the Residential Exposure Joint Venture (REJV), which has developed a national survey regarding residential consumer use/usage data for pesticides which help form the basis for exposure assessments. The REJV is planning to conduct a similar survey to update the existing data to reflect current trends.

This Notice explains why these data were developed, discusses plans for additional data development, and indicates how registrants who may wish to rely on and/or participate in the development of these data may join the REJV. The Notice identifies Environmental Protection Agency (EPA) and REJV contacts for persons wanting further information.

II. The use of REJV data under the Federal Pesticide Regulatory Scheme

The Federal Food, Drug and Cosmetic Act (FFDCA) requires EPA to consider available information concerning dietary and non-dietary exposure when assessing a pesticide's risks, especially to children. The evaluation of potential pesticide exposures in and around residences presents unique challenges due to the complex and dynamic nature of this environment. Exposures can occur because product application and human activities overlap in affected microenvironments but such exposures can vary because pesticide use and human behaviors result in exposure that differs on both a spatial and temporal basis. Residential exposure to pesticides may involve multiple sources because a product is used in more than one way in a residence. Similarly, more than one product containing the same active ingredient may be used. These differences can result in multiple exposure sources from different exposure pathways and through different routes of exposure. Potential exposure pathways include treated lawns or indoors sources. Routes of exposure include dermal exposure through contact and oral ingestion through the mouthing behaviors of children.

The REJV was formed in August 1997 to collect, organize and analyze label and use information for pesticide products used in and around the home. This information aids in the conduct of exposure assessments for the use scenarios associated with specific pesticide active ingredients including how to aggregate their exposures as appropriate across routes and pathways. It has also been used to assist with the development of cumulative risk assessments under the FFDCA for classes of chemicals that share a common mode of toxicological action which requires combining exposures for all chemicals in the class.

An important part of EPA's regulatory process is having information to determine how a pesticide is used in household settings and its ability to characterize exposures associated with

that use. For example, consider a pesticide that is applied by a certain fraction of U.S. households to control pests indoors and also applied by yet another group of users to control pests outside their homes. Certain households use the pesticide for both types of applications. For products registered exclusively for indoor use, the use determination is fairly straightforward. However, for some proportion of U.S. households, outdoor uses may also occur resulting in multiple product applications and/or potential post-application exposure scenarios resulting in overlap or "co-occurrence" across time which indicates multiple types of exposures have to be appropriately considered. This example illustrates why determination of residential use and exposure characterization is an important part of EPA's regulatory process. Further, without a firm basis for estimating potential co-occurrence of pesticide product use and exposures EPA cannot conduct refined probabilistic aggregate and cumulative risk analyses. EPA believes that product use information over time as developed by the REJV has and will continue to be an important part of EPA's risk assessments, including its probabilistic aggregate and cumulative assessments

Without reliable product data regarding how and how often a product is used (use and usage information), EPA's residential and consumer product assessments must instead rely on "default" assumptions regarding product use-related input variables used to estimate potential applicator (handler) and post-application exposures. REJV's objective for its original survey as well as its future efforts was and is to survey consumers to develop a comprehensive database of residential use and exposure data on consumer pesticides to provide EPA with real world use information that allows the Agency to refine its assessments. Applicants and registrants seeking to rely on REJV data to satisfy any applicable EPA data submission requirements, including the development of related exposure models, must comply with the applicable provisions of sections 3(c)(1)(F) and 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) regarding data compensation.

III. Objectives of the REJV

This information is provided by the REJV to describe both its past and future planned efforts to provide U.S. and international pesticide regulators with reliable, real world residential product use information. The REJV obtained input from the EPA, California EPA and Canada PMRA in its development and conduct of a calendar or diary-based survey (May 2001 – April 2002) to determine the demographics and spatial (geographic) characteristics of households using the products, and temporal use information (beyond currently available label information). These data include an assessment of residential characteristics, area of residence treated, amount of product used over time and per treatment, pests treated, and product use co-occurrence. The goal was to obtain basic information about pesticide product use in and around residential sites in a form that permits "mapping" individual and concurrent product use events over time. The duration of the original survey instrument was 12 months. The survey design provided a nationally representative "static" sample of households during the 12 month time period. The REJV has also created an information management system that houses both label- and use-related information. The major objectives of the system included the following:

- Provide key label related information (from EPA's Pesticide Product Information System) such as registration number, formulation type, % A.I., application method and rate, area treated, use instructions, precautionary statements, etc.). that can be cross-referenced with
- Survey-based use information such as EPA registration number, product name, application method, date of application, frequency and timing of use, site of application, and user demographics generated through the conduct of the 12-month diary survey program.

Regulatory changes that have taken place since the completion of the REJV survey in 2001 (such as the removal of various Organophosphates and Carbamates from residential uses) and the subsequent market and consumer adjustment to find replacement pesticides, have resulted in significant changes in use and usage patterns, especially for pyrethroids. Therefore, the REJV is planning to conduct a similar survey to "refresh" the existing data to reflect current trends and chemistries.

IV. Use of Residential Exposure Surveys in Connection with EPA Regulatory Actions

EPA considers relevant, available use information to inform its non-dietary exposure assessments as part of a registration application or amendment, as well as in the re-registration and registration review process. EPA has relatively few surveys or studies assessing product use information in and around residences that can specifically inform residential exposure assessments to pesticides. In the absence of reliable data that can be used to accurately assess product use and inform such exposures, EPA will use appropriate, protective estimates, modeling, or assumptions to assess potential exposures. The development of consumer household product use and usage information by REJV has provided EPA with a more accurate basis for assessing these exposures in some instances. EPA expects to have a continuing need for such information, including updated surveys that better reflect current usage. For this reason, the Agency expects that it will require submission or citation of such data in connection with upcoming registration reviews and other regulatory actions.

Any pesticide registrants or applicants who believe they may need to satisfy these data requirements may wish to consider participation in the REJV. When EPA imposes requirements to submit or cite product use/usage data, the registrant or applicant electing to rely on REJV data must, at the appropriate time, inform the agency of its election of this option and provide evidence of its membership in the REJV or certify that it has offered to compensate the REJV for reliance on their data in accordance with EPA regulations. In the event that the REJV and a non-member who cites REJV 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.

V. Current Members

Current Members of the REJV are: BASF, Bayer Environmental Science, McLaughlin Gormley King Company, S.C. Johnson & Son, Inc., Syngenta, Inc., United Industries, and Valent Biosciences.

VI. Contacting the REJV

Those desiring further information on the Task Force may contact the following:

Stuart McArthur, Chairman, Steering Committee, Residential Exposure Joint Venture, S.C. Johnson & Son, Inc., 1525 Howe Street, M.S. 149, Racine, WI 53403.
Phone: (414) 260-2405
Fax: (414) 260-4716
Email: semcarth@scj.com.

Susan Little, Executive Chair, Pesticide Ingredient Review Program,
Consumer Specialty Products Association,

900 17th St., NW, Washington, D.C.
Phone: 202.872.8110
FAX: 202.872.8114
E-mail: slittle@cspa.org

VII. Agency Contact

For questions or further information regarding the REJV, please contact:

David J. Miller, Chief
Chemistry & Exposure Branch
Health Effects Division
Office of Pesticide Programs
703-305-5352 (voice)
703-305-5147 (fax)



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Steven Bradbury, Ph.D., Director
Office of Pesticide Programs
U.S. Environmental Protection Agency