



US Environmental Protection Agency Office of Pesticide Programs

Pesticide Registration (PR) Notice 2011-2

Non-Dietary Exposure Task Force

November 23, 2011

**Pesticide Registration (PR) Notice
2011-2**

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

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

SUBJECT: Non-Dietary Exposure Task Force

I. Introduction

This PR Notice is to advise registrants of an industry-wide task force, the Non-Dietary Exposure Task Force (NDETF), which has developed and is developing data to support the quantitative evaluation and assessment of potential residential/consumer exposures to pesticides products. This Notice updates an earlier Notice, PR 2000-7, which initially announced the formation of the NDETF. This Notice describes data that have been and are being developed, explains the need for these data, and indicates how registrants who may wish to rely on and/or participate in the development of these data may join the NDETF. The Notice identifies Environmental Protection Agency (EPA) and NDETF contacts for persons wanting further information.

II. The use of NDETF data under the Federal Regulatory Scheme

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requires EPA to consider available information concerning dietary and non-dietary routes of exposure when assessing a pesticide's risks, especially to children. The FFDCA also requires EPA to consider aggregate exposures to a pesticide from food, water and residential use. EPA must also consider cumulative exposures from multiple chemicals that share the same mode of action.

The evaluation of potential aggregate and cumulative pesticide exposures in and around residences presents unique challenges due to the complex and dynamic nature of this environment. Potential exposures can occur as the result of the spatial and temporal interaction of product application and human activities in affected microenvironments. Residential exposure assessments for pesticides may involve more than one source (i.e., more than one product may be used per household), and multiple pathways and routes. For example, a given pesticide active ingredient (AI) may be found in a product applied by a homeowner to control pests indoors, and for a certain fraction of U.S. households, the same ingredient may be found in another product applied by the same homeowner outside their home. In addition to possible exposure during the application of these products, homeowners may engage in certain post-application activities that may result in exposure opportunities by the inhalation, dermal and/or incidental ingestion routes. Determination of how a given pesticide is used in consumer and professional products and the subsequent fate, transport and occurrence in exposure media (e.g., indoor air,

accessible indoor floor surfaces) is a critically important risk evaluation component for EPA's registration and re-registration process. Further, given the need for EPA to conduct probabilistic aggregate and cumulative risk analysis, realistic assessments need to be based on data that provide an empirical basis for estimating potential distributions of exposure to pesticide products during toxicologically relevant time periods. This requires spatial and temporal exposure data. Until the NDETF data were developed, few studies were available to address the information necessary for developing robust aggregate and cumulative non-dietary exposure assessments. Additionally, existing data sources provided only limited, if any, temporal data needed to establish profiles of pesticide residues in the indoor environment following the use of common product forms (e.g., indoor total release foggers, and aerosol sprays including hand-held and stationary fixed mounted).

Without reliable exposure data such as the NDETF data, residential and consumer product assessments generally rely on EPA-developed "default" assumptions regarding exposure assessment-related input variables used in predictive equations to estimate potential applicator (handler) and post-application exposures. Such assumptions are conservative by design, and may therefore result in overestimation of exposures to various consumer products. The NDETF's main objective is to develop a comprehensive database of residential exposure data on consumer pesticides in place of default assumptions. These data are also intended to address specific EPA requirements for exposure data. As such, EPA anticipates using the NDETF data to inform decisions and to satisfy certain data requirements on registration and registration review activities for consumer use pesticide active ingredients (AIs). Applicants and registrants seeking to rely on NDETF data to satisfy any applicable EPA data submission requirement, including the development of related exposure models, must comply with the applicable data compensation provisions of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) §§ 3(c)(1)(F) and 3(c)(2)(B).

III. Objectives and Scope of the NDETF

This information is provided by the NDETF to describe both data it has developed and data it intends to provide U.S. and international pesticide regulators with scientifically sound data to improve the accuracy of assessments of non-dietary exposures (primarily residential, and some occupational scenarios) to natural pyrethrins and associated synergists (PBO and MGK 264). The NDETF was formed in June 1996 to generate data on exposure levels associated with residential and some occupational uses of natural pyrethrins (PY), synthetic pyrethroids and associated synergists piperonyl butoxide (PBO) and MGK 264 (N-octyl bicycloheptene dicarboximide), to inform EPA's human health risk assessments conducted under both the FFDCA and FIFRA. The NDETF drew members from the Pyrethrin Joint Venture (PJV) and Piperonyl Butoxide Task Force II (PBOTFII), two Task Forces set up in the 1980s by producers, formulators, and marketers of the AIs to respond to re-registration needs. The PJV and PBOTFII were formed to develop toxicology and crop residue data to support the re-registration of PY and PBO. In addition, both groups recognized the need for a comprehensive and integrated approach to exposure and risk assessment. Because PY and PBO, as well as

another synergist, MGK 264, are commonly used together in formulated products, the member registrants decided to combine efforts and form a single entity: the NDETF. Very early in its history the NDETF, with input from EPA, broadened its data generation effort to span the pyrethroid pesticides family, and the group opened its membership to all pyrethroid manufacturers. To that end, the NDETF's extended its data development to cover the full range of active ingredients from PY and the photolabile pyrethroids to the photostable pyrethroids (e.g., permethrin), to the alpha-cyano pyrethroids (e.g., deltamethrin) and to other AIs when supported by the science. The plan was to develop the needed data to establish generic transfer factors that could be applied to the entire class of pyrethroids and the synergists (The NDETF refers to this conceptual framework as "The Bridge."). As the program progressed, the NDETF conducted studies with formulations containing PBO and the synthetic pyrethroids permethrin and deltamethrin. Thus, the NDETF believes its data are relevant to all pyrethrin- and pyrethroid-based pesticide products used in and around the home that are being evaluated for specific product use scenarios, and for aggregate and cumulative exposure and risk assessments under the FFDCA).

The NDETF worked closely with EPA, California EPA and Health Canada's PMRA to develop a program of research and data development that was needed to strengthen the scientific basis for residential exposure assessment (and for selected occupational exposure scenarios). The NDETF focused its data development efforts on the following two elements of the EPA priority list:

- 1) Temporal and spatial distribution of pesticides after residential use;
- 2) Dermal and non-dietary ingestion exposure assessment methods and exposure factors.

Examples of data development efforts completed by the NDETF include:

- Comparison of post-application transferable residue sampling methods
- Single and Multiple hand press from treated surfaces
- Transfer from treated surfaces to dry and wet hands
- Saliva removal efficiency of pesticides from hands
- Transfer from the skin to other surfaces
- Temporal aspects of transferability
- Exposures during and after the use of pet care shampoo products
- Human post-application exposure (passive dosimeter versus biomonitoring associated with choreographed reentry activities)

Historically, empirical data needed for rigorous risk assessment were lacking; therefore, as noted, EPA had to use default assumptions to ensure that its exposure assessments are protective. Against this backdrop, the NDETF began to develop experimentally based empirical exposure data. The NDETF data also represent an important advance in risk assessment because they facilitate the development of probabilistic assessments of potential residential exposure. In addition to replacing the default assumptions with empirical measurements, the NDETF data are being used to produce more statistically

robust distributions for the various parameters, so that probabilistic assessments can be performed. This approach is directly relevant to EPA's proposed revisions to the residential exposure assessment Standard Operating Procedures (SOPs)¹, which encourages use of higher-tier probabilistic modeling using distributional input data.

The NDETF data submitted at this time represent a major advance in the knowledge as to many of the parameters that are key to residential exposure assessment. These studies will allow for more reliable and accurate estimates of exposure than would be possible using current default assumptions. Further, the NDETF database provides scientifically "reliable information" necessary to support refined (e.g., probabilistic) residential exposure and risk analyses in support of compound-specific re-evaluation activities.

IV. EPA's Regulatory Position

EPA considers relevant, available use information to inform non-dietary exposure assessments as part of a registration application or amendment, as well as during registration review activities for existing pesticides. EPA has relatively few studies addressing aspects of exposure monitoring, particularly following product application in residential environments. Some of these data are chemical- and formulation-specific and other data can be used in a more generic manner. In the absence of reliable data that can be used to accurately assess and inform such exposures, EPA will use appropriate estimates, modeling, or assumptions to assess potential exposures. The development of exposure study data provides EPA with a more accurate basis for assessing these exposures. EPA has determined that development of reliable exposure data is necessary to support applications and existing registrations as reflected in various data requirements in the "875 Guidelines". For this reason the Agency has utilized, and will continue to utilize, relevant NDETF and other data that satisfy these requirements in risk assessments to inform pesticide registration and re-evaluation decisions. More specifically, some already submitted NDETF data were used in EPA's recently completed cumulative assessment of the pyrethrins and pyrethroid insecticides. This cumulative assessment relies on certain default assumptions resulting in conservative estimates of exposure and risk. The data generated and being generated by the NDETF are expected to be helpful in reducing uncertainties associated with conservatism in this assessment. EPA also anticipates that the NDETF data will be used in assessing individual pyrethrins and pyrethroid insecticides being reviewed under the pesticide registration review process and when considering requests for registering new uses.

EPA currently requires Applicator Exposure and Post-Application Exposure data as part of its Series 875 Human Exposure Guidelines (see tables below). The NDETF data are generally suited to address these data requirements for those pesticides addressed by the NDETF database (with the exception of 875.1700, 875.2100 and 875.2700).

¹ U.S. EPA (2009). Draft Technical Guidelines - Standard Operating Procedures for Residential Pesticide Exposure Assessment Submitted to the FIFRA Scientific Advisory Panel For Review and Comment, September 2009. Office of Pesticide Programs, Office of Prevention, Pesticides, and Toxic Substances, U.S. Environmental Protection Agency, Washington, DC.

Table 1. Applicator Exposure Data Requirements

Guideline Number	Data requirement	Use pattern	
		Occupational	Residential
875.1100	Dermal outdoor exposure	R	R
875.1200	Dermal indoor exposure	R	R
875.1300	Inhalation outdoor exposure	R	R
875.1400	Inhalation indoor exposure	R	R
875.1500	Biological monitoring	CR	CR
875.1600	Data reporting and calculations	R	R
875.1700	Product use information	R	R

Table 2. Post-Application Exposure Data Requirements

Guideline Number	Data Requirement	Use Pattern	
		Occupational	Residential
875.2100	Dislodgeable foliar residue and turf transferable residues	R	R
875.2200	Soil residue dissipation	R	CR
875.2300	Indoor surface residue dissipation	R	R
875.2400	Dermal exposure	R	R
875.2500	Inhalation exposure	R	R
875.2600	Biological monitoring	CR	CR
875.2700	Product use information	R	R
875.2800	Description of human activity	R	R
875.2900	Data reporting and calculations	R	R
875.3000	Nondietary ingestion exposure	NR	R

Pesticide registrants or applicants who believe they need to satisfy exposure-related data requirements may wish to consider participation in the NDETF. When EPA imposes requirements to submit or cite exposure data or should an applicant, registrant, or other task force otherwise rely on NDETF data to support or maintain registrations, the registrant or applicant electing to rely on the data must, at the appropriate time, inform the Agency of its election of this option and provide evidence of its membership in the NDETF or certify that it has offered to compensate the NDETF for reliance on their data to the extent required by FIFRA. In accordance with FIFRA, in the event that the NDETF and a non-member who cites NDETF 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 FIFRA §§ 3(c)(1)(F) and 3(c)(2)(B).

VI. Current Members

The current members of the NDETF are:

BASF Corporation
Bayer CropScience LP
Botanical Resources Australia
Endura S.P.A.
McLaughlin Gormley King Company
Pyrethrum Board of Kenya
Prentiss Incorporated
S.C. Johnson & Son, Inc.
Takasago Int'l. Corp., USA
Valent BioSciences Corporation

VII. Contacting the NDETF

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

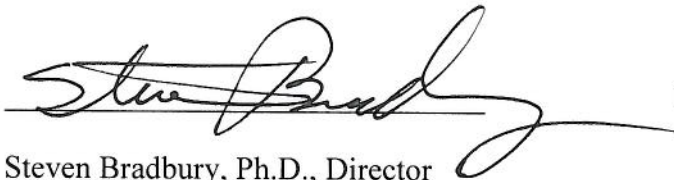
Nasser Assaf, Ph.D., Chairman, Technical Committee, Non-Dietary Exposure Task Force
Manager, Product Safety and Regulatory Affairs
Valent BioSciences Corporation
Environmental Science Division
Phone: 847-968-4844
E-mail: nasser.assaf@valentbiosciences.com

Susan Little, Executive Chair, Pesticide Ingredient Review Program,
Consumer Specialty Products Association,
900 17th St., NW, Washington, D.C.
Phone: 262.872.8110
FAX: 202.872.8114
E-mail: slittle@cspa.org

VIII. Agency Contact

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

David J. Miller, Chief
Chemistry & Exposure Branch
Health Effects Division
Office of Pesticide Programs
Phone: 703-305-5352
FAX: 703-305-5147
E-mail: Miller.David@epa.gov



Dated: 11/10/11

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