

US EPA ARCHIVE DOCUMENT

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PART B - CHAPTER 9
NONDIETARY INGESTION EXPOSURE ASSESSMENT

9.1 INTRODUCTION

This Guideline provides a description of the methods and computational factors that may be used to assess postapplication nondietary ingestion exposure to pesticides. Nondietary ingestion exposure may occur as a result of: (1) inadvertent ingestion of soil that contains pesticide residues; (2) ingestion of pesticide-treated foliage, pesticide granules/pellets (e.g., used to treat residential lawns) or pesticide-laden paint chips; and (3) hand-to-mouth or object-to-mouth transfer of pesticide residues that have accumulated on the hands or objects that have come in contact with pesticide residues on indoor surfaces such as carpet, countertops, or hard flooring or on lawns or other outdoor surfaces, e.g., soil. The nondietary ingestion route may be particularly important for infants and children exposed to lawn chemicals and household pesticide products in residential settings because of the incidence of hand-to-mouth activity (Hawley, 1985) or object-to-mouth activity (Reed et al., 1997) and the activities performed by children (e.g., crawling) that put them in close proximity with treated surfaces (U.S. EPA, 1998a; 1998b). Children described (American Academy of Pediatrics, 1990; Bredekamp, 1985; U.S. EPA, 1998a) as crawlers and walkers (ages 8 to 18 months) and toddlers and two-year olds (18 months to three years of age), spend a substantial portion of their time indoors. A child's greater surface area to body weight might make increased dermal exposure more hazardous (Wolff and Schechter, 1991; Snodgrass, 1992). Nondietary ingestion exposure may be estimated using residue data for the media of interest (i.e., turf, soil, indoor surfaces) and standard ingestion rates, based on the age group or activity of interest. Assessment of nondietary ingestion exposure requires compliance with various other Guidelines presented in Series 875, Group B (i.e., Part B, Chapters: 4 Transferable Residue Dissipation: Lawn and Turf; 5 - Soil Residue Dissipation; and 6 - Indoor Surface Residue Dissipation).

9.2 SAMPLE COLLECTION

9.2.1 Test Substance

The test substance to be used for nondietary postapplication exposure assessments must be a typical end-use product. Where metabolites or breakdown components of pesticide end-use products pose a potential toxicological concern, investigators may need to consider sampling on a case-by-case basis.

9.2.2 Timing of Application

Testing should be conducted during the intended use season. If outdoors, weather forecasts should be studied, as much as possible, to avoid initiating testing immediately (e.g., within 24 hours) before a precipitation event.

9.2.3 Pesticide Application Rate and Frequency

Generally, the typical end-use product chosen for the study should be applied at the maximum rate specified on the label. In addition to applying the product at the maximum label rate, it is suggested that the product be applied using a lower rate. For example, typical rates are often used in cancer assessments (U.S. EPA, 1997). Monitoring at more than one rate will provide additional information about the relationship between the application rate and the residues available for nondietary ingestion. Also testing at a lower rate may prove to be beneficial in the event that the data from use of the product at the maximum application rate results in an unacceptable risk.

9.2.4 Sampling and Assessment Parameters

Sampling parameters should be based on the following criteria:

- Residue deposition and dissipation data should be collected from the types of surface media associated with the typical use of the product. If the product is used indoors, then the surface media might be carpet, vinyl and wood flooring, and/or sheetrock (U.S. EPA, 1998c). If the product is used outdoors, then the surface media might be lawn, soil, and/or foliage. Registrants should discuss with EPA the surface media to be sampled during protocol development.
- Residue deposition and dissipation data for the media of interest should be collected from at least three environmentally distinct locations of varying temperature and relative humidity per formulation type (U.S. EPA, 1998c). Refer to the appropriate chapters for guidance concerning the types and numbers of samples that are appropriate.
- The sampling period should be of long enough duration and sampling intervals within the sampling period should be selected to adequately characterize dissipation. For dissipation sampling, at least three replicate samples should be collected from representative sampling environments at each sampling interval. See Part B, Chapters 4, 5, and 6 for additional information on sampling requirements.

- Highly exposed (or sensitive) populations should be evaluated (e.g., ingested dose among children is higher than for adults because of the higher rates of soil ingestion) (U.S. EPA, 1996).
- As a high-end, acute estimate, postapplication exposures should be estimated for the day of application for residential scenarios. Subchronic or long term exposures should be assessed using dissipation data for the media of interest.

9.2.5 Sampling Techniques

The selection of a sampling method will depend on the nondietary pathway(s) of interest. Investigators should consider all potential pathways of nondietary ingestion exposure (e.g., soil ingestion plus hand-to-mouth transfer and object-to-mouth transfer of surface residues) that are applicable,

9.2.5.1 *Inadvertent Soil or Dust Ingestion*

Soil or dust may be ingested by children and adults as a result of normal mouthing behaviors. Incidental soil or dust ingestion may be associated with activities such as children playing on treated areas (i.e., yards or playgrounds, or in indoor settings) or adults performing gardening activities in treated areas. Inadvertent soil ingestion exposure may be assessed using soil or dust residue data and standard soil or dust ingestion rates for various age groups [i.e., the product of soil or dust residue concentration (mg/g) and soil or dust ingestion rate (mg/day) yields potential dose (mg/day) from nondietary soil or dust ingestion]. See Part D, Chapter 2 - Calculations for more information on the calculations required for estimating exposure from incidental soil ingestion. Soil should be collected and analyzed for soil pesticide residues based on the guidance provided in Part B, Chapter 5 - Soil Residue Dissipation (Guideline 875.2200). Dust may be collected and analyzed based on guidance provided in Part B, Chapter 6 - Indoor Surface Residue Dissipation. Soil and dust ingestion rates should be based on the recommended age-specific values provided in U.S. EPA (1996). Additional guidance for assessing nondietary soil ingestion exposure is provided in U.S. EPA (1998a).

9.2.5.2 *Ingestion of Pesticide-Treated Foliage*

Pesticide-treated foliage may be ingested by toddlers playing on treated residential turf or playgrounds as a result of mouthing behaviors. Exposure to pesticides from nondietary ingestion of pesticide-treated foliage may be assessed using dislodgeable foliar residue data and estimates of the amount of foliage that children may be likely to ingest while playing outdoors [i.e., the product of dislodgeable foliar residue concentration (mg/g) and foliage ingestion rate (mg/day) yields potential dose (mg/day) from

nondietary ingestion of treated foliage]. See Part D, Chapter 2 - Calculations for more information on the calculations required for estimating exposure from incidental ingestion of treated foliage. Treated foliage should be collected and analyzed for dislodgeable residues based on the guidance provided in Part B, Chapter 4 - Transferable Residue Dissipation: Lawn and Turf (Guideline 875.2100). Ingestion rates for foliage should be based on the weight of the estimated area of turf ingested, as provided in U.S. EPA (1997).

9.2.5.3 *Ingestion of Pesticide Granules/Pellets, or Paint Chips*

Dry pesticide materials in the form of granules/pellets, or paint chips may be ingested by toddlers who play in pesticide-treated areas (i.e., yards, gardens, playgrounds, or home treated with pesticide-containing paints). Exposure from inadvertent ingestion of pesticide granules/pellets may be assessed using the fraction of pesticide active ingredient in the granules/pellets and a standard ingestion rate [i.e., the product of the fraction of active ingredient in the dry pesticide formulation and the ingestion rate of granules/pellets (mg/day) yields potential dose (mg/day) from ingestion of dry formulation]. Ingestion exposure for paint chips may be assessed using information on the percent of active ingredient in the paint, and a standard ingestion rate for paint chips. Studies to evaluate the dissipation of pesticide active ingredients in dry pesticide formulations and paint should be proposed to the Agency in the study protocol, on a case-by-case basis. See Part B, Chapter 2 for the factors that should be considered when designing a residue dissipation study. See Part D, Chapter 2 - Calculations for more information on the calculations required for estimating exposure from ingestion of granules/pellets, or paint chips. Additional guidance for assessing nondietary ingestion exposure from pesticide granules/pellets and paint chips is provided in U.S. EPA (1997).

9.2.5.4 *Hand-to-Mouth Transfer*

Pesticide residues may be transferred to the skin during postapplication contact with treated indoor (i.e., carpet or hard surfaces such as floors or countertops) or outdoor areas (i.e., turf or foliage). Nondietary ingestion exposure from hand-to-mouth transfer and object-to-mouth transfer may be assessed using transferable residue data for the surface area of the hands of children and standard assumptions regarding the frequency of hand-to-mouth and object-to-mouth activity. The mass of residues ingested may be calculated for various age groups as the product of the transferable residue concentration (mg/cm²), frequency of hand-to-mouth or object-to-mouth activity (events/day), and surface area contacted from which residues are ingested (cm²/event) to yield potential dose (mg/day) from hand-to-mouth transfer. See Part D, Chapter 2 - for more information on the calculations required for estimating exposure from hand-to-mouth transfer. Depending on the scenario of interest (i.e., indoor or outdoor) dislodgeable residues should be assessed based on the guidance provided in Part B, Chapter 4 - Transferable Residue Dissipation: Lawn and Turf (Guideline 875.2100) or Part B, Chapter 6 - Indoor Surface Residue Dissipation (Guideline 875.2300). The frequency of hand-to-mouth activity may be based on data in U.S. EPA (1998a) and data on surface areas of the hands

for specific age groups may be based on data from U.S. EPA (1996). Additional guidance for assessing nondietary ingestion exposure from hand-to-mouth transfer is provided in U.S. EPA (1998a).

Recently, EPA's National Exposure Research Laboratory (NERL), Human Exposure and Atmospheric Sciences Division (HEASD) designed a program to explore the pediatric and behavioral science literature for activities such as hand-to-mouth or object-to-mouth activity that could be used to explain nondietary exposures (U.S. EPA, 1998a). Statistical prior or "premodel" distributions of activities were to be established based on demographic characteristics. These premodel distributions were to be tested in field studies at day care centers where the behavior of children could be both observed directly by experts and videotaped. These studies would be expected to produce a data base of "postmodel" distributions for certain patterns of behavior that could be studied under controlled laboratory conditions using adult human subjects to measure dermal contact and transfer of surface residues by whole-body dosimetry. The aim of the research was to reduce or eliminate the need for exposure studies that require human subject participation. U.S. EPA (1998a) summarized data taken from the open literature on the duration and extent of hand-to-mouth and object-to-mouth activity, sorted according to predictor variables. The predictor variables included factors such as age, sex, ethnicity, and socioeconomic status. The literature review demonstrated the relative importance of the factors impacting nondietary ingestion exposure. These data may be useful for assessing nondietary exposure from hand-to-mouth or object-to-mouth activity for the population of interest.

9.3 SAMPLE STORAGE

In general samples should be stored in a manner that will minimize deterioration and loss of analyte between collection and analysis. Sample storage techniques should be consistent with the guidance provided for the media of interest (i.e., soil, indoor residues, foliar residues etc.) for the nondietary ingestion scenario being evaluated, as described above. Detailed information on sample storage is provided in Part C, Quality Assurance and Quality Control. The study investigator is responsible for demonstrating stability of the samples under the storage duration and conditions used.

9.4 SAMPLE ANALYSIS

Appropriate cleanup procedures should be used and the pesticide residues quantified by the best available method for the media of interest. See Part C, Quality Assurance and Quality Control for more detailed information on sample analysis.

9.5 CALCULATIONS

Refer to Part D of this document for a description of the calculations needed for estimating exposure and risk.

9.6 DATA PRESENTATION

Data on nondietary ingestion exposure should be presented as the mass (mg) of active ingredient per day, or as an average daily dose or lifetime average daily dose (mg/kg/day), for the population(s) and exposure scenario(s) of interest.

REFERENCES FOR PART B, CHAPTER 9

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