PART B - CHAPTER 7

DERMAL EXPOSURE

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GUIDELINE 875.2400

7.1 INTRODUCTION

This Guideline provides a description of the techniques commonly used to measure dermal exposure via passive dosimetry. The dermal exposure data generated using this guidance will serve as the basis for regulating chemicals in various settings, including agriculture, industry, and the residential market. This regulation will be based on the exposure and risk assessment process using the data. Additionally, dermal exposure data can be used in conjunction with concurrently gathered ambient chemical dissipation data to establish chemical transfer coefficients. (See Part B, Chapters 3 through 6.) These transfer coefficients can be used in the exposure and risk assessment process to predict exposures for specific activities using ambient residue concentration data in the absence of scenario-specific exposure data (e.g., to develop Restricted Entry Intervals for agricultural harvesters using dissipation data generated in another region).

7.2 SAMPLE COLLECTION

7.2.1 Test Substance

As stated at 40 CFR 158.390, the test substance to be used for dermal exposure measurements must be a typical end-use product. Where metabolites, breakdown components, or contaminants of pesticide end-use products pose a potential toxicological concern, investigators may need to consider sampling for them on a case-by-case basis.

7.2.2 Timing of Application

Sampling should be conducted during the intended use season or under climatic conditions that are essentially representative of those anticipated during the intended use season. Weather forecasts should be studied, as much as possible, to avoid initiating the testing immediately (e.g., within 24 hours) before a precipitation event. For further information on climatological considerations, see Part B, Chapter 2 - Study Design.

7.2.3 Pesticide Application Rate and Frequency

Generally, the 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 application rate. For example, the typical rate is often used in cancer assessments (U.S. EPA, 1997). Monitoring at more than one rate will also provide additional information about the relationship between the application rates, deposition rates, and transfer coefficients. 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.

Where multiple applications are recommended, the minimum time interval between applications should be used. Also, the potential accumulation of residues from multiple applications should be considered. The application method and equipment typical for the selected test substance should be used.

7.2.4 Sampling Parameters

Sampling parameters should be based on the following criteria:

- A sufficient number of replicates should be generated to address the exposure issues associated with each population of interest. In general, each study should include a minimum of 15 replicates per activity. Where possible, these replicates should be distributed as follows: 5 replicates (i.e., individuals) on each of three monitoring periods (i.e., "n" days after application). Investigators must be flexible concerning the number and distribution (i.e., locations and intervals after application) of the monitoring replicates. Because the aforementioned guideline cannot be expected to apply to all potential scenarios, the Agency requires investigators to submit protocols for review purposes prior to the inception of a study.

- The exposure monitoring period must be of sufficient length to have reasonable detectability of residues on dosimeters, and be representative of a normal activity. The activity must be well defined, and representative of typical practice. Most postapplication activities range from 4 hours (i.e., harvesting roses/chrysanthemums in a greenhouse) to 8 hours (i.e., harvesting strawberries). Thus, a representative monitoring duration based on typical activities is recommended for each replicate. Justifications for determining monitoring durations should be provided in study protocols.

- Changes of clothing, gloves, or samples during the workshift should occur in the case of breakthrough or to coincide with natural breaks in the day. Hand rinse and wash sampling intervals should be instituted when the test subjects routinely clean their hands, at scheduled breaks (e.g., lunchtime) and at the end of the exposure monitoring period. If the

representative exposure activity is of a short duration (e.g., 4 hours), one handwash is sufficient.

- Passive dosimetry studies must be carried out concurrently with transferable residue studies. Refer to the appropriate chapters for guidance concerning the types and numbers of transferable residue samples that are appropriate.

- The selected sites and seasonal timing of monitoring must be appropriate to the activity. The need for studies under different geographical/climatological sites should be considered.

- Monitoring should be conducted before residues have dissipated beyond the limit of quantification.

7.2.5 Sampling Techniques

The passive dosimetry techniques for measuring dermal exposure discussed in this Guideline include patches, whole-body dosimeters, hand rinse and wash, gloves, and fluorescent tracer. The selection of the proper technique is dependent upon several factors including activities being monitored, environmental conditions (e.g., heat stress), and physical/chemical properties of the active ingredient.

The Agency recommends whole-body dosimeters instead of patches. However, little to no research has been published to compare and/or validate these two techniques. Both techniques have advantages and disadvantages; the Agency accepts both for outdoor exposure studies. However, whole body dosimeters are essential for proper study of residential indoor exposures. The uncertainties associated with these methods include:

- Protective backing is used in the construction of monitoring patches to prevent the penetration of collected residues. Whole-body dosimeters, however, generally consist of long underwear garments or coveralls worn next to the skin with no protective backing. Due to the lack of an impermeable barrier, the potential for residues to penetrate through whole-body dosimeters exists. This potential could result in whole-body dosimeters underestimating exposure.

- Monitoring patches cover a limited surface area of a body part and are used to extrapolate exposure to the entire body location. Incidental contact or nonuniform deposition of pesticides onto the test subject's monitoring patch can under- or over-estimate exposure (Fenske, 1990). The Agency believes that nonuniformity is less critical in reentry exposure monitoring scenarios because of the physical nature of the contaminant compared to distributional differences noted with pesticide handlers (i.e., because of handling concentrated material).

With respect to monitoring hand exposure by hand rinse/washes, the Agency is concerned about the inadequacy of associated field recovery techniques that start with fortifying the rinsate. Such methodology fails to account for the ability of the dosimeter (in this case, the hands) to trap or retain residues under a variety of environmental and/or physiological conditions. In addition, there is a failure to account for extraction efficiency of the solvent for removing residues from the hand. Fenske and Lu's (1994) findings of handwash removal efficiency indicated that substantial amounts of chlorpyrifos were either absorbed through, or adsorbed to, the skin and that two to five-fold underestimates of exposure may occur. These deficiencies in the monitoring technique may produce an underestimation of actual hand exposure. The use of lightweight cotton glove dosimeters, which may be directly fortified for field recovery determination, minimizes these problems when used for exposure monitoring. Data in the literature indicate that cotton gloves provide a higher residue than the handwashes for the same activity (Fenske et al., 1989, Davis et al. 1983). The Agency recommends that the study investigator address these concerns when selecting and developing a hand exposure monitoring methodology.

Investigators also need to select the location (i.e., inside or outside clothing) of the monitoring devices. If investigators select outside placement of dosimeters, additional uncertainties are built into the risk assessment by the addition of clothing penetration factors. Although the Agency's preferred location of the dosimeters is under typical work clothing, the selected locations should be based on the use scenario. If a typical clothing scenario dictates the need, both internal and external monitors should be used for evaluation of a variety of clothing scenarios.

7.2.5.1 *Patch Dermal Dosimeter*

The patch dermal dosimeter method measures dermal exposure via absorbant patches that are attached to specified areas of a workers body, either inside or outside the clothing. Patches of predetermined size serve as collection media for the pesticide and surrogates for measuring the amount of pesticide contacting the clothing or skin. Subsequent to the performance of postapplication exposure activities, the patches are removed and analyzed for pesticide content. The quantities of pesticide on patches from a specified location on the body are used in conjunction with standard body surface area data for those body parts to estimate potential dermal exposures. Differences between pesticide deposition on inside and outside patches can be used to determine clothing penetration factors. A comprehensive review of the "patch" (i.e., pad) sampling methodology is available in Durham and Wolfe (1962), Wolfe (1976), and Davis (1980).

Patch Composition and Size. The composition and size of the patches used in dermal dosimetry studies are important considerations and should be based on the physical/chemical characteristics of the pesticide and the exposure scenario. For example, patches may be constructed from papermaking pulp (e.g.,

alpha-cellulose) or a similar material. A high quality alpha-cellulose will absorb a considerable amount of residue without disintegrating. Another material, that is satisfactory and more readily available in small lots, is preparative chromatography paper. Other appropriate materials include surgical gauze, clothing material, and blotter paper. In extremely dusty environments, investigators should consider patch materials that are porous enough to collect dusts or dried residues. Surgical gauze is suggested as an appropriate material for dry formulations. Typically, patch materials should not require preextraction to remove substances that interfere with residue analysis. This should, however, be determined before beginning exposure tests using such patches. Patches should be approximately 1 mm thick and backed with an impermeable material such as aluminum foil, polyethylene, or glassine paper. These materials will reduce the potential for contamination of the patches by materials on the skin or clothing and prevent seepage of collected residues through the patch to the skin or clothing. Multilayered patches are not considered to be suitable for determining penetration. Instead, evaluation of penetration of work clothing should be conducted using inside and outside patches, as described below. Patches should be constructed or used in multiples per sampling location so that the exposed area is approximately 10 cm x 10 cm (100 cm^2). The use of smaller patch areas is generally inappropriate and should be avoided.

Attachment and location of patches. Patches should be attached, according to the exposure situation, to collect residues representative of those impinging on all regions of the body. Normally, a complete set for each exposure period will consist of 10 to 12 patches. Patches should be attached under the test subject's clothing as depicted in Figure B7-1. The patches should be attached directly on the test subject's skin or to the inner clothing. The patches should not be attached to the inside of the outer clothing because these pads would not collect chemicals or residues penetrating through the openings of the clothing. Patches should be attached at the following locations: top of the shoulders, back of the neck just below the lower edge of the collar, the upper chest near the jugular notch, back of the forearms, and front of the thighs and lower legs. Inside patches must be centered under seams as well as under unseamed material, because seams are often the areas of maximum penetration. If the workers are engaged in some activity that is likely to result in extraordinary exposure to regions of the body that are not well represented by the usual patch locations, extra patches must be included to assess such exposure. If the determination of actual penetration of work clothing is desired in the field study, additional patches can be attached to the worker's outer garments. The use of multilayered inside patches is not suitable. Care must be taken to ensure that any patches attached to the outer clothing are near, but not covered by, patches under the clothing. Patches may be attached to the skin using material such as surgical tape which will hold the patches during vigorous activities. Patches may be attached to clothing using safety pins, staples, or tape. Some investigators have utilized specially designed harnesses or lightweight vests fitted with open-fronted pockets to hold the shoulder, chest, and back patches. These

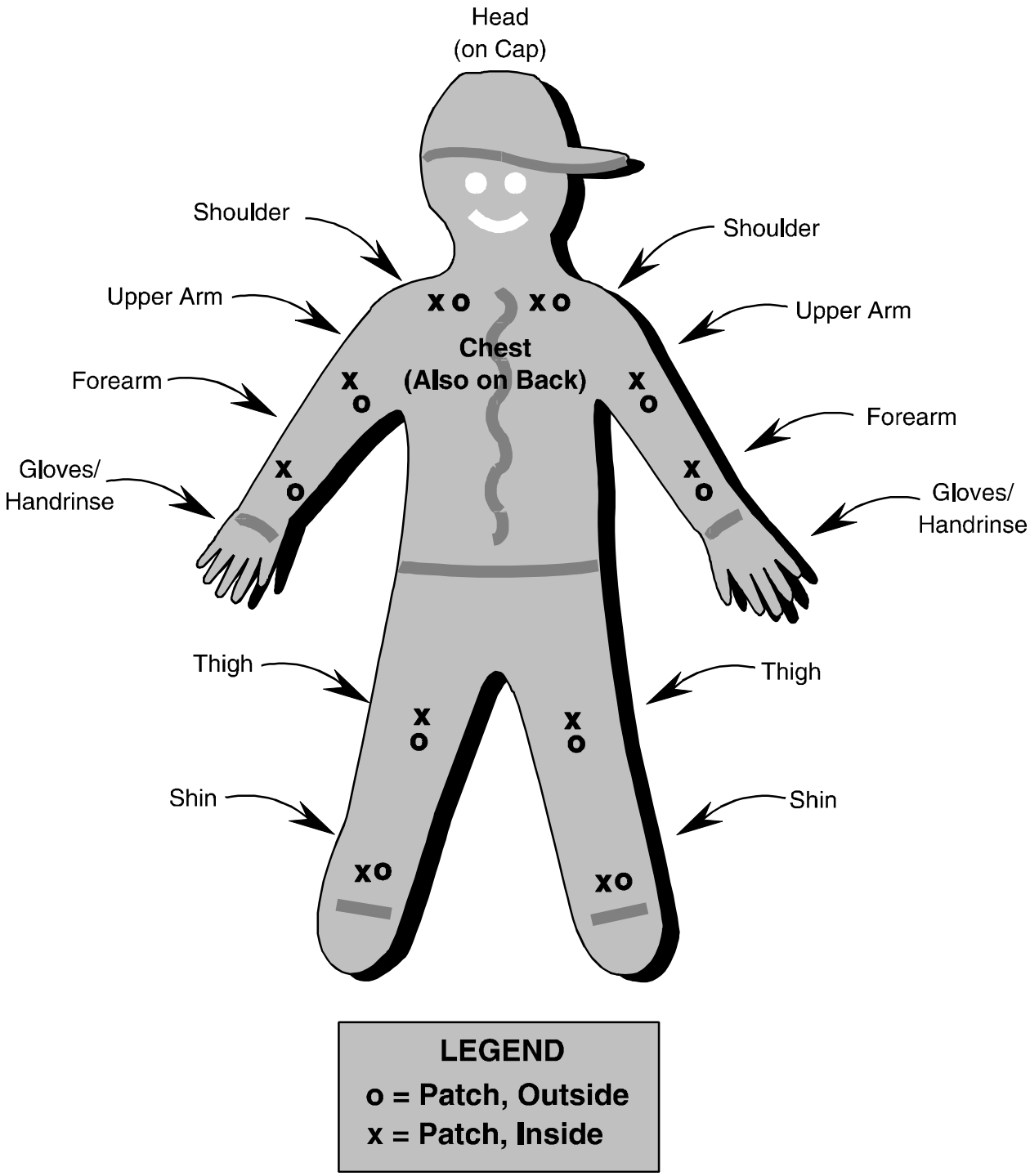

Figure B7-1. Patch Locations

alternative attachment methods have been used successfully and are acceptable. The patches should be evaluated for potential contamination or losses from/to adhesives or holders.

Removal and handling of patches. The procedure for handling exposed patches will depend on the stability of the pesticide(s) being studied. If the prefield study results indicate that the pesticide is stable on moist exposure patches, then the patch should be placed in a prelabeled protective envelope or bag in a manner that avoids both cross-contamination with its holder and residue loss from contact with the envelope. All bags containing exposed patches from one exposure of a single test subject should be grouped together. Care should be taken to not contaminate the patches in handling. If the prefield study results indicate that the pesticide is unstable, the investigator needs to provide a method of handling the patches that is documented prior to the study.

7.2.5.2 *Whole Body Dosimeter*

Another dosimetry method for measuring dermal exposure is the whole body technique. This technique uses a whole body dosimeter to trap pesticides that would otherwise contact the skin. Whole body dosimeters have been used under a variety of circumstances, including for registration purposes. They have also been used as research tools to monitor exposures during specific activities (see discussion of Jazzercise TM, Part B, Chapter 12 - Description of Human Activity).

Composition of the whole body dosimeter. A whole body dosimeter can be defined for the purposes of this document as an article of clothing (including socks) that is useful for monitoring total dermal exposures. It should be constructed of suitable absorbant material such as cotton or cotton/ polyester. Several options are available to investigators (WHO, 1982; Abbott et al., 1987). Standard whole body dosimeters that are generally accepted include commercially available white cotton socks, long-sleeved cotton tee shirts, and thermal underwear bottoms and tops. Whole body "Union" type suits or lightweight coveralls are acceptable to measure exposure as long as the material is of sufficient thickness to avoid penetration that may occur when saturated. Investigators can select the particular articles of clothing from a wide variety of commercially available choices (e.g., sizes, suppliers, fabrics, elastic waist, ankle bands, etc.).

Durability and availability should be considered by investigators as key issues when making selections. The standard dosimeters mentioned above should be capable of withstanding the mechanical forces (e.g., abrasion, snagging, tearing, etc.) exerted during routine activities of the test subjects. Such postapplication agricultural activities may include, but are not limited to, harvesting, maintenance operations, scouting, and planting. Physical durability is critical; if dosimeters are not intact at the end of an exposure monitoring period, they are useless.

Availability of the garments selected as the whole body dosimeters is another critical issue. Investigators must be careful to purchase sufficient quantities of garments to ensure that all dosimeters used in a study for measuring a particular type of exposure are of the same type (e.g., fabric blends) and from the same production lot, if possible. Obtaining dosimeters from the same or similar production lots is critical because it allows direct comparison of exposure results. Also, blanks and fortified samples should be used to evaluate contamination and recovery rates by production lot or batch.

A variation of the whole body dosimeter method uses typical work clothing (i.e., based on the activity and prevailing weather conditions) as the sampling media (Chester, 1993). The advantage of this technique is that exposure may be estimated by dermal dosimetry and biological monitoring simultaneously (Chester, 1993). However, if single layer typical work clothing is used as the dosimeter (i.e., total deposition), a clothing penetration factor will be needed to estimate the amount of residue contacting the skin.

Required facilities. The need for various facilities is self-evident in the discussion of whole body dosimeters. Test subjects must be afforded privacy when donning and removing the garments used as whole body dosimeters. Changing rooms must remain free from contamination with the test substance or other chemical contaminants during preparations for a field trial.

Removal and sectioning of whole body suits. Upon completion of an exposure monitoring period, investigators must be careful to ensure sample integrity. Proper sample collection procedures are critical to minimize loss of test material and prevent contamination of the dosimeters. After exposure, dosimeters should be removed and sectioned for storage, extraction, and analysis. Consideration should be given to turning the dosimeters inside out to minimize loss of test material after removal, based on the type of formulation used. This procedure may be more suitable for liquids than dry formulations since powders may be lost in handling. Investigators must be especially careful to avoid cross contamination of the exposed dosimeters during removal and sectioning. Typically, test subjects will be required to wear total body dosimeters underneath their normal work clothing to simulate the adsorptive/absorptive surfaces of bare skin protected by normal work clothing. Because this is the case, test subjects' normal work clothing will act as a protective "filter" through which the pesticide residues must pass prior to being retained by the dosimeter. As a result, test subjects' clothing must be treated by investigators as being a potential source of cross contamination. Investigators should develop sample collection procedures that minimize cross contamination. For example, to obtain a representative sample, test subjects may be asked to do the following, with assistance of a technician: (1) wear rubber gloves while removing their outer clothing; (2) discard the initial pair of rubber gloves and replace them with a clean pair; then (3) remove and section the total body dosimeter and place it into sample storage containers. At a minimum, whole body dosimeters are typically sectioned by investigators into arms, torso, and legs. Sectioning of dosimeters should also occur

in a manner that minimizes cross contamination. Sections should be handled in sequential order of anticipated increasing contamination.

The Agency recognizes that communication between test subjects and investigators is critical. This is never more apparent than when total body dosimeters are collected. Investigators, therefore, are required to be able to communicate clearly with test subjects. Interpreters should be available, if needed. As an example, total body dosimeter samples can easily be invalidated by cross contamination through several mechanisms, including but not limited to, the following examples: (1) test subject places sample on floor or chair in changing room; (2) test subject touches sample wearing rubber gloves used to remove outer clothing; or (3) outside surfaces (i.e., highest anticipated residue levels or nonprotected "skin") of test subject's outer clothing contact surfaces of dosimeter. Post-exposure changing facilities potentially can be highly contaminated with the pesticide(s) being studied because it is normal for test subjects to become dirty during their work activities. Contamination in changing facilities can occur when dirt and dusts retained by the workers' clothing and shoes are shaken off during sample collection procedures.

7.2.5.3 *Hand Rinse and Wash*

Exposure via the hands often accounts for a significant portion of total dermal exposure. Thus, monitoring hand exposures is an important part of a dermal exposure study. Hand rinse sampling has been used for monitoring dermal hand exposure. Prior to conducting a study in which hand rinse techniques are used, participants should be required to wash their hands in an appropriate solvent to remove any background contaminants present.

Materials used. Several types of solutions can be used to collect hand rinse samples. These range from various types of aqueous surfactant solutions to neat isopropanol or ethanol. Investigators are free to select which types of solutions can be used. Investigators, however, must also be careful to consider the physical/chemical properties of the pesticide(s) being studied. For example, if a pesticide is water soluble, then an aqueous surfactant solution should be used instead of a neat alcohol (i.e., octanol water partition coefficient (K_{ow}) may be used as an indicator of a chemical's water solubility). Sufficient quantities of hand rinse solutions should be prepared prior to field trials to avoid the chance of cross contamination during solution preparation in the field.

Water used for preparing aqueous solutions should be distilled and deionized; however, either deionized or distilled water is sufficient if no alternatives exist. Water, used in the preparation of the aqueous surfactant solutions, may be purchased from commercial vendors. If commercial water is used, investigators should try to obtain sufficient quantities from the same lot and supplier. If the water used in a study is

tapwater purified by the performing laboratory (i.e., distilled and/or deionized), the equipment used to prepare the water must be described in the report. Investigators must be careful to use the same water source throughout all phases of a study. Several commercially available surfactants can be used to prepare hand rinse solutions (e.g., Sur-Ten, Aerosol OT-75, and Nekal WT-27). In general, hand rinse solutions should be diluted and otherwise prepared in a manner congruent with that described for the dislodgeable foliar residue solutions. (See Part B, Chapter 3.)

Neat alcohols (e.g., isopropanol or ethanol) may also be used as hand rinse solutions. The same factors described above regarding the purchase/preparation of water for use in the aqueous hand rinse solutions also apply to alcohols. Investigators must use pesticide grade solvents if neat alcohols are to be used as hand rinse solutions.

Sampling procedure. Investigators use a wide array of techniques to obtain hand rinse samples. Some investigators opt for minimal mechanical agitation, while others routinely employ it in their sampling methods. The Agency, however, recommends that mechanical agitation be used. Various procedures can be used to introduce agitation and, therefore, theoretically, mechanical removal of residues from the skin's surfaces (Durham and Wolfe, 1962). These procedures can include, but are not limited to: (1) a hand rinse procedure in which test subjects wash their hands in a routine fashion, or (2) a procedure in which hands are placed in individual polyethylene bags containing a hand rinse solution and are then shaken vigorously for at least 2 minutes. All field procedures must be carefully documented in any submission to the Agency.

7.2.5.4 *Sampling Gloves*

Gloves provide investigators with an alternative technique for monitoring dermal hand exposure. As with the hand rinse technique described above, participants should be required to wash their hands in an appropriate solvent to remove background contaminants before putting on the dosimeter gloves. If protective gloves are worn by the study participants, dosimeter gloves should be worn underneath.

Materials. A wide variety of lightweight absorbant cloth gloves are commercially available. Durability and availability should be considered by investigators as key issues when selecting a glove for use as a field dosimeter. Physical durability is critical; if the gloves are not intact at the end of an exposure monitoring period, they are useless. The standard dosimeters should be capable of withstanding the mechanical forces (e.g., abrasion, snagging, tearing, etc.) exerted upon them as a result of the routine activities of the test subjects. Such postapplication activities may include harvesting, maintenance operations, scouting, and planting. While white "pall bearers" gloves have a number of advantages as hand dosimeters, they lack the physical strength for some activities. Various knit gloves (sometimes labeled

"pickers gloves") are a more rugged alternative. As with all dosimeters, gloves should be pre-tested to ensure that they do not contain materials that might interfere with the pesticide residue analysis.

Availability of the selected gloves is another critical issue. Investigators must be careful to purchase sufficient quantities of gloves to ensure that all dosimeters used in a study for measuring a particular type of exposure are of the same type (e.g., fabric blends) and from the same production lot, if possible. Obtaining gloves from the same or similar production lots is essential because it allows direct comparison of exposure results.

Removal of sampling gloves. Upon completion of an exposure interval, investigators must be careful to ensure the integrity of the samples. Proper sample collection procedures are critical. Investigators must develop sample collection procedures that prevent cross contamination. For example, to obtain a representative sample, test subjects should peel the gloves away (i.e., turn inside out) from both hands, then place the gloves into a sample storage container(s).

7.2.5.5 *Fluorescent Tracer*

Dermal exposure can be quantified indirectly and non-invasively by measuring deposition of fluorescent materials. The use of fluorescent compounds can be coupled with video imaging measurements to produce exposure estimates over virtually the entire body (Fenske et al., 1986a, 1986b 1993). This requires pre- and post-exposure images of skin surfaces under longwave ultraviolet illumination, development of a standard curve relating dermal fluorescence to skin-deposited tracer, and chemical residue sampling to quantify the relationship between the tracer and the chemical substance of interest as they are deposited on skin. Imaging analysis has been applied primarily to pesticide mixers and applicators (Fenske, 1988; Methner and Fenske, 1994a, 1994b), but has also been applied to workers handling treated lumber (Fenske et al., 1987), to children contacting turf following tracer applications (Black, 1993), and to greenhouse applicators (Archibald, 1995).

Ideally, this method could provide improved accuracy in dermal exposure assessment because it measures actual skin loading levels (i.e., the skin serves as the collection medium) and it is extremely sensitive in a qualitative fashion. In practice, however, it has several important limitations: (1) use of a tracer requires the introduction of a foreign substance into the production system; (2) the relative transfer of the tracer and chemical substance of interest must be demonstrated during field investigations, (3) additional quality assurance steps may be required during field studies, including range-finding and the evaluation of potential tracer degradation due to sunlight; and (4) when protective clothing is worn, separate studies may be required to determine the relative fabric penetration of the tracer and the chemical substance of interest.

Important considerations in the use of fluorescent tracer technique include the following: (1) performance of the tracer/dye as a suitable surrogate should be tested prior to use in the field study, (2) the tracer/dye should not alter the physical properties of the pesticide formulation, and (3) the clothing penetration features of the tracer/dye should be the same as those of the pesticide.

7.2.6 General Considerations for Field Sample Collection

Sufficient control samples should be collected so that fortified controls can be prepared on each sampling day. These fortified controls should be packaged, transported, stored, and analyzed concurrent with the dermal exposure samples. (See Part C, Quality Assurance and Quality Control).

7.3 SAMPLE STORAGE

Samples should be stored in a manner that will minimize deterioration and loss of analyte between collection and analysis; more detailed information on sample storage is provided in Part C, Quality Assurance and Quality Control. The study investigator is responsible for demonstrating the stability of the samples under the storage duration and conditions used.

7.4 SAMPLE ANALYSIS

Validated methods of appropriate or sufficient sensitivity are needed for all sample analyses. See Part C, Quality Assurance and Quality Control for more detailed information on sample analysis.

7.5 CALCULATIONS

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

7.6 DATA PRESENTATION

Individual body locations and total residue data should be reported in tabular form. The residues should be reported as μg or mg of pesticide active ingredient per body part sampled if generated using the whole-body dosimetry technique and on a surface area basis if the data were generated using the patch technique (i.e., normalized on patch sample surface area; ug/cm^2 or mg/cm^2). Distributional data should be provided, to the extent possible.

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