SAP Report No. 98-01
November 19, 1998

REPORT

FIFRA Scientific Advisory Panel Meeting, October 14-15, 1998, held at the Embassy Suites Hotel, Arlington, VA

Sets of Scientific Issues Being Considered by the Environmental Protection Agency Regarding:

I - Review of Guidance Document for Small-Scale Prospective Ground Water Monitoring Studies
II- Review of Proposed Revised Guidance for Conducting Terrestrial Field Dissipation Studies

Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel,

Washington, DC

The Scientific Advisory Panel (SAP) was established under the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Food Quality Protection Act (FQPA) of 1996, to provide advice, information, and recommendations to the EPA Administrator on pesticides and pesticide-related issues regarding the impact of regulatory actions on health and the environment.

The major objective of the Panel is to serve as the primary scientific peer review mechanism of the EPA, Office of Pesticide Programs (OPP). Further information about SAP reports and activities can be obtained from its website at http://www.epa.gov/pesticides/SAP/ Interested persons are invited to contact Larry Dorsey, FIFRA SAP Executive Secretary, via e-mail at dorsey.larry@epamail.epa.gov or the OPP Docket at (703) 305-5805.

SAP Report No. 98-01A, November 19, 1998

REPORT:

FIFRA Scientific Advisory Panel Meeting , October 14, 1998, held at the Embassy Suites Hotel, Arlington, VA

I - A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding:

Review of Guidance Document for Small-Scale Prospective Ground Water Monitoring Studies

FOR THE CHAIRPERSON:

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Paul I. Lewis
Designated Federal Official
FIFRA/Scientific Advisory Panel
DATE:_____________________

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT
SCIENTIFIC ADVISORY PANEL MEETING

I - A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Review of Guidance Document for Small-Scale Prospective Ground Water Monitoring Studies

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The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed its review of the set of scientific issues being considered by the Agency regarding review of the guidance document for small-scale prospective ground water monitoring studies. Advance public notice of the meeting was published in the *Federal Register* on September 14, 1998. The review was conducted in an open Panel meeting held in Arlington, VA, on October 14, 1998. The meeting was chaired by **Dr. Ernest E. McConnell** of Toxpath, Inc. **Mr. Paul Lewis**, SAP staff member, served as the Designated Federal Official.

Participants

Members of the Scientific Advisory Panel:

Dr. Jack Barbash, USGS National Water Quality Assessment Program
Dr. Richard Bull, Battelle Pacific Northwest Laboratories
Dr. George Hallberg, The Cadmus Group
Dr. Robert Hill, University of Maryland
Dr. Robert Horton, Iowa State University
Dr. Russell L. Jones, Rhone-Poulenc Ag Co.,
Dr. Ronald Kendall, Texas Tech University
Dr. Sam Kung, University of Wisconsin
Dr. Fumio Matsumura, University of California at Davis
Dr. Herbert Needleman, University of Pittsburgh
Dr. Christopher Portier, National Institute of Environmental Health Sciences
Dr. Ali Sadeghi, USDA Agriculture Research Service
Dr Tammo S. Steenhuis, Cornell University
Dr. Mary Anna Thrall, Colorado State University
Dr Ian van Wesenbeeck, Dow AgroSciences

Oral statements were received from the following individuals:

Mr. Thomas Gilding (American Crop Protection Association)
Dr. Sunmao Chen (Novartis Crop Protection)
Dr. Aldos Barefoot (DuPont Agricultural Products)
Dr. Daniel Dyer (Bayer Corporation)

No written statements were received.

Summary of Agency Presentations

The goal of a prospective ground-water monitoring (PGW) study is to track the movement and measure the concentrations of an applied pesticide, its degradates of concern, and a conservative tracer from the surface of a study site through the vadose zone to ground water. Data derived from PGW studies are used both in human health and environmental risk assessments. The Agency believes that PGW studies provide some of the best targeted ground-water monitoring data available for many pesticides, and often the only ground-water monitoring data for degradates of concern.

Mr. Kevin Costello opened the Agency's presentation, commenting on the goals and uses of a prospective ground water monitoring study. Dr. Robert Matzner discussed site selection and characterization. This presentation focused on selection of a site that would provide the information necessary to satisfy the study objectives and assess site vulnerability relative to pesticide use. Dr. Laurence Libelo discussed monitoring plan design and identified techniques and parameters (e.g. number of samples, irrigation needs) required for the study. Dr. Michael Barrett closed the Agency's presentation by commenting on monitoring plan implementation and use of study results.

Agency Questions and Panel Responses

The Agency presented the following questions to the FIFRA SAP regarding review of guidance document for small-scale prospective ground water monitoring studies. The questions are keyed to the Agency support document *Guidance for Prospective Ground Water Monitoring Studies*. The Panel used the term "pesticide compounds" to denote either pesticide parent compounds or their transformation products (degradates). References to the Agency support document (ASD) are given as page and paragraph numbers (e.g. p. 14, ¶1).

GENERAL COMMENTS ON AGENCY SUPPORT DOCUMENT

Overall quality of Agency support document

The Panel expressed the opinion that the document is generally well written and appears to incorporate much of what has been learned over the past ten years about pesticide transport and fate in the subsurface. In addition, the explicit acknowledgment of the importance of identifying and analyzing for major pesticide degradates is commendable.

Importance of summarizing and learning from previous work

The Panel emphasized the importance of using the results from current and previous ground water monitoring studies to support and inform the design of future studies of this type. One Panel member stressed this point stating that these [prospective] studies are individually of minimal value and represent what is practical, rather than the best science can offer. Although studies conducted at individual sites provide potentially important information about the sources, transport, and fate of pesticides in ground water, such studies are much less informative than a large collection of investigations at different sites with different chemicals. Furthermore, unless existing data have been evaluated and summarized in a readily accessible format, their value for guiding or eliminating the need for additional monitoring studies (p. 11) cannot be determined.

It is therefore proposed that the Agency give some consideration to the assembly of a working data base summarizing the principal design features and results from previous studies and to serve as an aid to the design of new investigations. One approach to the development of such a system might be to: (1) accelerate the conversion of the Pesticides-In-Ground-Water Data Base (PGWDB) to a computerized database format as soon as possible; (2) expand the PGWDB to include fields for a broad variety of site characteristics (e.g., soil properties, well construction and integrity, hydrogeologic setting, land-use features, climate, etc.) and study design features (e.g., nature of well selection process, analytical detection limits and recoveries) for each investigation; (3) include systematic summaries of the principal study conclusions with respect to specific hypotheses (e.g., relation between pesticide detection frequencies and pesticide use, influence of soil type, effect of agricultural management practices, etc.) in the PGWDB and; (4) update the PGWDB by adding this information for all studies conducted to date (the current version of the PGWDB covers studies from 1971-1991 only).

An updated database of this type could be used to assemble a summary of the results from all known previous investigations for a given pesticide before initiating any new studies for that compound (e.g., for pesticides undergoing reregistration or registering new uses). Alternatively, in the absence of any field data for the compound in question, comparable data for compounds with similar properties and use—rather than just laboratory and modeling results (p.15, ¶3)—could be used (p.14 [¶1]). For example, thorough summaries of the results from earlier investigations on alachlor and metolachlor would have provided considerable guidance for the design of recent studies on the transport and fate of acetochlor in the environment.

Only if study results are placed within the context of previous work will progress in understanding—and thus predicting—the environmental behavior and fate of these compounds be possible. If previous work continues to be disregarded, or even de-emphasized, this will result in "re-inventing the wheel" with each new investigation.

Treatment of preferential transport

The Panel expressed the opinion that the guidance document does not stress the importance of preferential transport in affecting the movement of some pesticides in the subsurface.

In general, there are two conceptual models of how pesticides move in the vadose zone. The first conceptual model is based on the convective-dispersive equation. For this model, the assumption is made that water and dissolved solutes sample all pore spaces. The pesticide front is assumed to be at a uniform depth below the surface (as long as the soil type is the same) and to move with a single, average velocity downward to the ground water. This velocity depends on the amount of water recharged, the field capacity, and the water-soil partition coefficient for the compound and soil in question (Koc or Kd).

The second conceptual model is the preferential flow model in which a portion of the total mass of pesticides applied (typically a relatively small portion, on the order of a few percent at the most) travels directly from the surface to the ground water with the first major recharge event (typically, rainfall or snowmelt) following application. This phenomenon has been observed in a number of studies in all humid parts of the United States. There are two types of preferential flow: macropore flow in structured soils and a combination of funnel and unstable fingered flow in sandy soils.

The type of monitoring proposed is primarily based on the convective-dispersive flow model; only in a few places is the preferential transport of pesticides addressed in the guidance document. For example, the assumption that sites with coarse textured soils with low organic matter content and high sand content are those most highly susceptible to leaching (p. 8) is justified only because the convective-dispersive approach is the model of choice. However, very high concentrations have been found in tile lines in structured soils shortly after application.

The perceived need for the PGW studies to account for the possibility of preferential transport is supported by the fact that the hypothetical pesticide Zapadoo was always found to be transported to depths in the soil horizon greater than those predicted by the plant root zone model (PRZM) simulations (p. 14, ¶2). Disparities of this nature between prediction (which typically assumes purely convective-dispersive transport) and observation are commonly reported in the literature.

The importance of accounting for preferential transport also is demonstrated by pronounced contrasts between the hydraulic conductivities measured in the field and in the laboratory on the same soil. One of the Panel members noted that soils defined by the National

Resource Conservation Service (NRCS) as having low hydraulic conductivity values of less than 0.5 cm/hr (and should therefore be excluded from the analysis) are the same soils as structured soils with high hydraulic conductivity (which are appropriate for high-exposure ground water monitoring). NRCS typically measures the saturated hydraulic conductivity on disturbed soil samples, resulting in a low conductivity value. In the field, the high conductivity is a result of the macropores and structural cracks in the same soil for which the disturbed soil sample yielded the low conductivity value given at the top of p. 23. The Panel provides greater comment on preferential flow in the site selection discussion of the document.

As noted earlier, the saturated hydraulic conductivity measured on disturbed soil samples, mentioned on p. 32, typically exhibits no relationship to the hydraulic conductivity measured in the field. For the saturated hydraulic conductivity to be meaningful, it needs to be determined on undisturbed cores or directly in the field. There are also a number of interesting methods (such as the Guelph permeameter) to measure the unsaturated conductivity directly in the field. Both hydraulic conductivity and the soil moisture characteristic curve can be determined in the field with the instantaneous profile method.

Sampling of tile drains

There was disagreement among the Panel members with regard to the value of sampling tile drains during the PGW studies. One Panel member expressed the view that tile drains provide access to water from the top of the saturated zone, and that sampling tile drains therefore represents one of the best methods for sampling shallow ground water. Consequently, the Panel member thought that the statement on p. 22 of the ASD "sites with drain tiles, drainage ditches, etc. may also need to be considered for some pesticide uses" should be more strongly worded toward actually recommending the sampling of tile drains during the PGW studies, where conditions warrant.

Another Panel member did not feel that residues in tile drains are representative of residues reaching ground water, and mentioned that recent work in areas with heavy soils in the U.K. suggest that the main channels to tile drains are formed as an artifact of the installation procedures. These channels, it was maintained, tend to be self cleaning and so can persist for many years.

Another comment was noted that past research comparing the chemical composition of water drawn from tile lines and shallow wells suggests only a moderate degree of agreement between the two. The chemical composition of tile drainage water therefore appears to be more representative of the quality of downward percolating water than that of the underlying ground water. As such, it would probably be best to use samples of tile drainage as a supplement, rather than as a substitute for those from shallow ground water. The effectiveness of tile drains at removing water from fields is also dependent on spacing and depth. Thus it is difficult to generalize that what is coming out of tile drains is representative of shallow groundwater.

Use of the term "dissipation"

It was noted that use of the term "dissipation" to be inherently imprecise because the term fails to differentiate between the effects of offsite transport to air, surface water or ground water, and (bio)chemical transformation. It was therefore suggested that use of this term be eliminated in favor of terminology that more precisely describes the fundamental governing processes in question. In making this suggestion, it was recognized that the word "dissipation" has a long history of use but, for example, it is also true that EPA has now begun to use the word "degradate" in place of the more traditional term "metabolite."

Use of terms "ground water" and "aquifer"

A point of confusion between the Agency and Panel members concerned the definition of the word ground water. In the document, it is generally assumed that all groundwater is derived from aquifers. The Panel did not consider this definition correct. An aquifer is considered as a saturated permeable geologic unit that can transmit significant quantities of water under ordinary hydraulic gradients, while ground water is defined as subsurface water that occurs beneath the water table in soils and geologic formations that are fully saturated. The many individual private drinking water wells that utilize shallow ground water are not all necessarily screened in aquifers. Furthermore, shallow ground water may be drained by agricultural tile lines.

Significance of "low" application rates

Throughout the document, it is assumed that low application rates do not pose a threat (for example, p. 10) . Low application rates might still be a problem, however, if the chemical is very toxic. Thus, requirements for a PGW study should be based on risk.

Other Comments

Disturbed soil samples (p. 31) do not reveal the fine layering and the macro pores in the soil. Both features are extremely important for evaluating the movement of pesticides through the soil. It is, therefore, important that the soil cores remain intact.

Breakthrough curves should also be measured for an undisturbed soil column. Breakthrough curves should be used to determine dispersivity and likelihood of preferential flow and to estimate an effective porosity for the soil sample.

The wording on p. 34 shows a bias against sites with preferential transport of pesticides: "Soil structure or other features that may result in significant preferential flow should be noted and reported. Such features are typical and are not usually a basis for rejection of a potential site." The last sentence should probably read: "Such features are common and should be considered in selecting a potential site".

Adjuvants in pesticide formulations can have substantial impacts on the environmental transport and fate of the active ingredient, as well as on product toxicity when pesticide formulations come in direct contact with plants or animals (either target or non-target). Recent findings on the dramatic difference between the amphibian toxicity of glyphosate alone and that of some of its commercial formulations demonstrate this the importance. Panel members differed, however, on whether fate assessments should account for the effects of adjuvants on the environmental transport and fate of pesticides, or on their toxicity to non-target organisms. While one Panel member maintained that chemical analyses for adjuvants are unnecessary because the concentrations of adjuvants are very dilute in soil water, another Panel member noted that there appear to be no published data to support this assertion.

Regardless of whether or not they include adjuvants, however, fate assessments should include citations for all of the studies upon which they are based, to enable readers to access and evaluate the studies on their own. Even if the documents themselves are confidential, some indication of the source of the information should still be provided (e.g., "Agrichem Corporation, confidential data").

There was no agreement on the appropriate approach to the chemical analyses of the tank mixture (p.43, ¶3). One Panel member noted that obtaining accurate estimates of the concentration of the active ingredient in the tank mix was extremely difficult. Another Panel member proposed to measure the concentrations of the active ingredient(s), the tracer and any adjuvants representing a certain minimum percentage of the original formulation (e.g., 1% by mass).

The section "Soil Water Content Measurements" (Page 45) is not completely accurate. Moisture content by itself cannot measure downward flux. For example, under steady state the moisture content profile with depth is constant, and thus the magnitude and direction of flow cannot be determined uniquely.

All measurements of field dissipation half-lives should be accompanied by the simultaneous measurement of the concentrations of all major transformation products.

Given the extremely low levels of analysis required by the Agency, several Panel members expressed the opinion that the maximum allowable reporting limits for parent and degradates should be set relative to a toxicological or ecotoxicological endpoint. Perhaps reporting limits should be set at one half of a specified endpoint for the most sensitive non-target relevant endpoint for the intervals specified. However, the Panel acknowledges that further clarification of which relevant endpoints should be considered.

In addition to the features listed on p.30, the base map should also indicate the locations of all nearby fields where pesticides are used.

<u>PANEL RESPONSE TO AGENCY QUESTIONS</u>

INTRODUCTION

(1) Are the results of studies conducted following this guidance useful and appropriate to determine if a pesticide can move to ground water under actual use and field conditions and resulting concentrations in ground water and drinking water?

Most of the Panel members concluded that the results from the type of PGW studies described in the Agency support document (ASD) are valuable for examining the transport and fate of pesticides in ground water, and for determining potential concentrations of pesticides and their degradates in ground water beneath areas similar to the study sites. The flexibility in the design and execution of these investigations is appropriate since the considerable variations in the physical and chemical properties of the applied pesticides must be accommodated by variations in the study design.

However, because concentrations of pesticides and their degradates in groundwater can be expected to vary significantly depending upon site characteristics, it should be noted that there is no general answer to address the question whether a pesticide or its degradates of concern move to ground water under actual use and field conditions.

According to one Panel member, a fundamental aspect of the discussion of these studies, raised by this question, appears to be in need of modification. Because of variations in their physical and chemical properties—and variations in site characteristics—the rates at which surface-derived solutes move through the subsurface will, of course, vary considerably from one compound and one location to another, but all pesticides applied to the land surface, like all other solutes, migrate in water flowing through the subsurface. Thus, it appears inappropriate to ask "whether" a pesticide, its degradates, or any other surface-derived solute will "leach" or "move" to ground water. Of principal concern to these and other related studies is the quantification of the rates at which the processes of solute transport, sorption and transformation occur—not "whether" they occur. Thus, a major change in the language of this document is in order; one that recognizes that all solutes "leach," but at varying rates, depending upon the balance among these various competing processes. Estimates of these rates can then be used to predict the amount of time required for the concentration of each analyte of interest to reach a particular value—either its analytical detection limit or some water-quality criterion—at a particular location in the flow system.

The guidelines address this question only for the worst-case conditions, examining only the issue of whether or not the compound reaches groundwater in the most vulnerable settings. The guidance does not describe how these numbers are used, or how the results will be extrapolated to more typical or less vulnerable use regions. The study is expensive if it is only used as one point in time and space for exposure and risk assessments. One Panel member thought that the level of effort put into these studies needs to be leveraged through the use of probabilistic modeling and extrapolation to other soils in the use area. Although it was recognized and agreed that modeling is not part of the guidance, the Panel member thought that the document would be improved by adding a clear statement regarding the purpose and value (or necessity) of modeling in extrapolating the results of these PGW studies.

In the current guideline, only measurements of pesticide concentrations in a soil profile or in groundwater are required. However, one Panel member commented that it is important to know whether the usage of a certain pesticide would cause a regional-scale groundwater contamination. In order to assess regional-scale groundwater contamination, it is necessary to determine mass flux of a pesticide into groundwater at discreet locations, as opposed to measuring pesticide concentrations at several random points. Thus, the Panel member concluded that the Agency should develop new guidelines to monitor and calculate mass flux of a pesticide into groundwater, instead of sampling pesticide concentrations. To accomplish this task, it is necessary to simultaneously determine pesticide concentration and water flux.

One Panel member commented that the guidance provided in the second paragraph (p.25) for requiring that point sources of contamination be assiduously avoided. It was suggested that any mention of the possibility that detections during a study may have been caused by point sources should be accompanied by a thorough description of the evidence upon which the claim was based. Another Panel member pointed out, however, that because these studies specifically avoid point sources, they are not useful for determining which pesticide compounds might be detected in ground water, at what concentrations, as a result of contamination from point sources or, for that matter, contamination caused by the influx of surface waters with detectable concentrations of pesticide compounds.

Although the studies are likely to provide estimates of the maximum concentrations of these compounds that might be encountered in drinking water derived from ground water, the maximum concentrations measured in ground water during the PGW studies are also likely to be considerably higher than those typically encountered in drinking water in vulnerable areas, because drinking-water wells are often installed at greater depths than most monitoring wells, and away from treated fields.

The ASD guidance implicitly acknowledges the need to develop a framework for the test that takes maximum advantage of the features of the test site. Such a framework needs to be reflected in the study design, and the plans for sampling and analysis should be developed accordingly.

The assumption that indoor pesticide use has a negligible effect on ground-water quality (p.10, ¶3) should be examined more closely, given the fact that previous studies have indicated a direct association between the frequency of detection of several of these compounds in groundwater (e.g., chlordane and heptachlor epoxide) and the density of development (especially residential, commercial, and institutional).

Partition coefficients and transformation half-lives should be provided for the parent compound and all major degradates. In addition, all data on transformation or dissipation rates, as well as partition coefficients, should be accompanied by the temperature(s) and pH values at which they were measured. Without this information, it is difficult to make comparisons among results from different studies.

One Panel member maintained that transformation rates—or, for that matter, partition coefficients or any other parameter than can be measured independently—should never be adjusted to improve fits between model predictions and field observations (p. 14, ¶2). Instead, it was thought that parameter values for model runs should be varied on a stochastic basis, based on the range of values reported in the literature.

(2) Are controlled field studies important to assess a pesticide's ability to move to ground water?

Although the question is somewhat vague, the Panel generally concluded that such studies are useful for gaining a better understanding of the sorption, transport and fate of pesticides in soils, subsoils, and ground water under actual use conditions. The controlled conditions make it possible to draw general conclusions about pesticide transport and fate that cannot be derived from the results of more ad hoc experiments conducted under less controlled circumstances. These studies are especially valuable if their data are to be used for modeling and extrapolation of the results to other use areas. The examination of the effect of increasing Koc with time (often attributed to the diffusion of the compound into less accessible, intraparticle pores in the soil and/or chemical binding to soil organic matter) is of particular importance.

However, a Panel member thought that much of this information can be obtained through field dissipation studies if soil samples are collected to an adequate depth and analyzed using methods with adequate sensitivity. Such soil sampling may inadequately describe the transport and behavior of these compounds in areas where preferential transport in vadose-zone water carries them below the depth at which they are no longer detected in the soil. The PGW study is especially relevant for observing the behavior of pesticide compounds in subsoils and their potential transformation in ground water if the study is appropriately augmented with downgradient wells.

3) Are the factors that OPP proposed to determine the need for a Prospective Ground-Water Monitoring Study appropriate given EPA's goals and the use of the results?

Most of the Panel members thought that the factors proposed for this purpose are generally appropriate. However, several expressed concern over the apparent absence of specific threshold, or "trigger" concentrations above which PGW studies might be required. Such threshold values should apply to the concentrations of either the parent compound or any of its major degradates (p. 20). One Panel member thought that these triggers should be based on toxicological data for the most sensitive non-target organisms that are likely to be exposed to these compounds in the areas where they are used—including nearby surface water into which contaminated ground water might discharge (p. 14, ¶4). Such information should be available before any monitoring studies are begun, to help set priorities among the analytes of potential interest. The term "level of concern" should be avoided unless it is given as a specific toxicological endpoint for a particular non-target organism.

It was noted that the reasons given (p.12) for the Agency's concern about the potential detection of any pesticide or major degradate in ground water are, in large part, poorly justified. Noting that "risk" is formally defined to be a function of both hazard and exposure, these reasons focused solely on exposure, with no apparent regard for the magnitude of the hazard involved. The Agency's expressed concern was too generalized and that the phrase "contamination of groundwater resources" by itself is insufficient to define the circumstances under which a compound poses a risk to humans or other non-target organisms. In particular, the word "contamination" was considered to be ambiguous and should therefore be explicitly defined in the document. However, in cases where hazard and exposure profiles combine to suggest that an unacceptable level of risk may be likely, then the five reasons for the Agency's concerns (p. 12) are legitimate.

Several Panel members concluded that the Agency should consider using the concentrations of pesticide compounds measured in water samples obtained from undisturbed column leaching experiments, or in-situ pipe or monolith lysimeters, to obtain conservative estimates ("intermediate tiers") of potential shallow groundwater concentrations for exposure assessments. For example, analyte concentrations measured in 1-m deep lysimeters could be combined with local or regional ground-water recharge data to estimate the concentrations of these compounds likely to be encountered in ground water. The significantly lower costs of running lysimeter studies would enable coverage (and thus assessment) of a much greater range of soils in most use areas. The validity of this approach would have to be demonstrated on the basis of results from previous studies that measured the concentrations of the compound(s) of interest (or similar compounds) in both ground water and in water sampled from the type of lysimeter of interest. Evaluations of pesticide leaching based on laboratory studies using disturbed cores (i.e., repacked soil columns) (p. 10) are poor predictors of leaching under field conditions and thus should not be used for the environmental fate assessment. Instead, the laboratory column studies on which these assessments are based should be conducted using undisturbed columns.

Once the risk thresholds are established for the pesticide of interest and its major degradates, mathematical simulations—using a computer model whose success in predicting observed solute concentrations in the field has been clearly demonstrated—can be used to estimate whether or not those concentrations are likely to be reached in the target media (soil, vadose-zone water or ground water) as a result of normal use. Opinions differed among Panel members on which computer models should be employed for this purpose. SCI-GROW may be a useful tool for some applications, but rarely should a decision be made on this simple tool alone. One Panel member thought that the best way to evaluate potential leaching is with more complex models such as PRZM 3.12, although others thought that any simulation model employed for this purpose should explicitly account for the effects of preferential transport.

One Panel member thought that, regardless of model results, PGW studies should rarely be necessary for compounds with Koc values exceeding about 200 mL/g because of the degree of sorption (Koc) is often seen to increase over time. The Panel member thought that for compounds with Koc values less than 200 mL/g, the potential to move to ground water is determined by the persistence and mobility (Koc) of the compounds; the rate, method and timing of application; and site characteristics such as soil properties, climatic conditions, and agricultural practices. Another Panel member noted, however, that Koc alone is a poor predictor of the likelihood of a pesticide being detected in ground water, as demonstrated by the observation that many pesticides with Koc values higher than 200 mL/g have been detected in ground water by several Statewide and multi-state monitoring studies over the past decade.

SITE SELECTION

(1) How important is it that study sites be located in areas of more vulnerable ground water?

General consensus of the commenters agreed that it is important to conduct the PGW studies in the most vulnerable regions of the use area for the compound(s) of interest, but most also thought that parallel studies should also be conducted at sites of more moderate (or "typical") vulnerability within the use area—an approach implied by the discussion at the end of the first paragraph on p.20. Computer models are valuable tools for anticipating variations in pesticide behavior across a range of vulnerabilities, but the models in current use are not sufficiently reliable to provide a satisfactory substitute for actual field observations in a variety of settings. Thus, studies conducted only in the most vulnerable settings—without the added benefit of complementary investigations from less vulnerable areas—will be of only limited value because they will provide only highly site-specific estimates of maximum potential exposures for humans and other non-target organisms.

An approach was suggested wherein a limited number of sites (usually no more than two) would be located in the most vulnerable regions of the use area; if unacceptably high residue concentrations are found in these areas, then additional investigations would be carried out in regions of the use area with more moderate vulnerability. If this occurred, though, it was not stated whether or not use should be prohibited in the settings in which the pesticide compounds were detected. Another Panel member noted that restrictions can always be placed on the use of pesticides in vulnerable areas. However, if the registrant has prevented use in some areas as a mitigation measure, it was recommended that the PGW studies should not be conducted in these areas.

The Panel noted that if neither the pesticide of interest nor any of its major degradates are detected in ground water at a site deemed to be highly vulnerable, a determination that the pesticide is not likely to reach ground water at concentrations of concern under those conditions is necessarily dependent upon the detection of the conservative tracer in the ground water at the site. If neither the tracer nor the test compound are detected in ground water at the site—despite having similar ratios of detection limit to initial concentration, to account for the effects of dilution and dispersion, the vulnerability of the ground water at the site in question may have been overestimated.

(2) **EPA has provided guidance as to what factors should be considered in identifying "typical" and "high exposure" study sites. Has EPA identified the most important factors to be considered? Should application rate also be considered as an important factor?**

Most of commenters agreed that the most important site-related factors appear to have been identified in this regard. However, some discussion of the relative importance of the different factors might have been in order. One Panel member recommended that ground water studies should continue to focus on coarse-textured soils, noting that although considerable downward movement can occur in fine-textured soils, vertical migration is substantially slowed at greater depths in such settings, with the most significant impacts occurring in surface water as a result of transport in tile drains and along the upper surfaces of low-conductivity horizons. In addition, the Panel member noted, widespread detections of pesticides in ground water tend to be more common in areas with shallow water tables and sandy soils.

Because pesticide detection frequencies generally tend to increase with increasing intensity of use, application rate should indeed be considered as an important contributing factor in site selection. However, given the relative insensitivity of pesticide detection frequencies to relatively minor variations in use (i.e., on the order of ±50%), variations in use among sites are only likely to be an important consideration for contrasts in application rate of factors of 3 to 5 or more.

(3) What are the relevant variables needed to determine the vulnerability of the study site and the use area?

Although Chapter 2 of the ASD contains descriptions of several characteristics of settings that are deemed to be highly vulnerable to pesticide contamination, the chapter does not appear to provide clear guidance on how the study site(s) should be related to the remainder of the pesticide use area with respect to variations in vulnerability. Some guidance is provided (p. 19), but there are relatively few data in the published literature that demonstrate the reliability of the vulnerability-assessment methods described.

The ASD states that indexing methods may be used by the registrant for assessing the vulnerability of ground water to contamination in different portions of the study area. However, several Panel members thought that indexing methods generally do not provide reliable estimates of vulnerability, and thus should not be used for this purpose. Simple GIS overlay methods are preferred, but only if they do not involve any arbitrary scoring or weighting procedures.

Since nitrate is more mobile in the subsurface than most pesticides (at least under aerobic conditions), one Panel member suggested the use of data on the spatial distributions of nitrate in ground water as a worst-case indicator of the vulnerability of ground water to contamination from surface-derived substances, such as pesticides, in the settings of interest. The distribution of nitrate in ground water has been relatively well characterized because it has been monitored routinely in rural ground water for many years. Moreover, this contamination has been occurring for a sufficiently long period of time that one might even be able to obtain some reasonable mass balance calculations. Another Panel member pointed out, however, that a large number of previous studies have investigated the extent to which nitrate concentrations in ground water may be used as an indicator for pesticide contamination, and that these efforts have demonstrated that nitrate is generally an unreliable indicator of pesticide contamination.

Parameters such as soil texture and depth to the water table can help in putting the vulnerability of a specific site in perspective compared to the entire use area. However, once selected, the types, locations and boundaries of the soil mapping units (p.23, ¶4; p.25, ¶4) should be verified by field inspection.

Information required on pesticide formulation (p.19, ¶1) should include the chemical names of all adjuvants and their approximate concentrations in their applied form. If possible, chemical analyses for the major adjuvants should also be conducted for the application mixture (p.43, ¶3) immediately prior to application.

SITE CHARACTERIZATION AND CONCEPTUAL MODEL

(1a) What is the minimum set of parameters needed to characterize the vadose and saturated zones so that a realistic conceptual model of the flow system can be developed?

Texture, pH and organic matter are all appropriate and should be measured on all samples. Consideration should also be given to including the sand size fraction, since most vulnerable sites are predominantly sand. Soil water content and saturated hydraulic conductivity seem appropriate. Bulk density would also be useful but may be affected by sample collection. The Agency should consider estimating all of the various hydraulic properties using estimation routines based on soil texture, bulk density, and organic matter. Hydraulic properties measured on disturbed samples, however, were considered to be of negligible value.

Several Panel members expressed the concern that Munsell color may also be of negligible value, particularly since it is not used as a model input. Other Panel members, however, pointed out that Munsell color is a parameter that has been widely used in describing and discriminating among different soil types, and might therefore be valuable for identifying specific soil units in soil surveys. This could, in turn, provide access to other parameters supplied by soil surveys that describe various physical and chemical characteristics of the soils of interest—variables that may, in fact, be useful for modeling efforts.

There was disagreement among Panel members about how to obtain estimates of some of the hydraulic properties of the vadose zone, as well as the value of such data. Noting that hydraulic conductivity-water content relations are expensive to determine, one Panel member suggested that these relations be estimated using pedo-transfer functions, in conjunction with texture and organic matter data or, alternatively, data on moisture retention. The Panel member thought that the collection of such data are of no value unless they are required for modeling efforts, and should thus be optional.

The use of soil hydraulic properties to draw inferences regarding solute movement through the unsaturated zone typically assumes that water and solutes move as a uniform front, with dispersion downward. Because water and solutes do not move down uniformly and most models have to be calibrated anyway, several Panel members thought that there is little justification for the level of detail in soil moisture characteristics and unsaturated conductivity curves that the guidance suggests gathering. Moreover, the results of most models are not very sensitive to the exact shape of the soil moisture characteristic curve at lower moisture contents. Of much greater consequence than the particular soil moisture retention curve or precise unsaturated soil conductivities used is the choice of the specific model used. It may therefore be unnecessary to measure all of the recommended soil water properties on all samples collected.

One Panel member expressed a preference for carrying out hydraulic measurements on undisturbed soil cores in the laboratory—measurements that are relatively straightforward to do. The advantage of undisturbed soil core studies is that a direct measure of leachability is obtained, rather than one inferred from models and soil characteristics. In addition, large undisturbed cores were thought to give a much better indication of leachability under field conditions than disturbed cores. Breakthrough curves can also be utilized to assess preference flow in undisturbed soil. Furthermore, the presence of preferential flow paths is not mentioned in the list of minimum requirements for selecting a potential site (p. 37) , despite the fact that preferential flow often causes early breakthrough of pesticides at high concentrations in ground water.

Since infiltration rate will vary according to tillage, it should not be used as a model input parameter. Furthermore, since the PGW studies are designed for minimal runoff, this variable should have very little effect on movement—assuming that equilibrium processes control the water movement in sandy soils. For situations where equilibrium processes do not control water and solute movement, however, the rate of infiltration will, indeed, be an important input parameter. Ground-penetrating radar could be used as a method for assessing variations in soil structure across individual field sites.

A soil profile has a spectrum of pores (i.e., from the soil matrix pores in the smaller end of the spectrum to the preferential flow paths in the larger end of the spectrum). The current measurements for site characterization suggested by the Agency focus on the adsorption and transport of contaminants through the smaller end of the spectrum. Thus, the Agency protocols are only suitable to determine contaminant transport through the soil matrix pores. Results from many field experiments have indicated that the main reason that a contaminant could reach groundwater was because of the transport through preferential flow pathways. Thus, one Panel member concluded that the Agency should develop new guidelines to quantify and sample the adsorption and transport of contaminants through the larger end of the soil pore spectrum. This new guideline will ultimately determine how many samples would be enough and how deep a sample should be collected.

In the current guideline, eight samples are required to determine the fate of a pesticide under field condition. The key issue is the locations of the samples, instead of the number of the samples. Because a contaminant will only be transported through very specific pathways, it is critical to monitor the transport through these pathways. If all samples are collected outside the preferential flow pathways, even 80 samples would not be enough to represent the deep leaching of a pesticide. However, if the preferential flow pathways can be characterized, only several samples along the pathways are necessary to accurately determine the total deep leaching.

Measurement of breakthrough curves for undisturbed soil samples should be conducted in order to estimate dispersivity, likelihood for preferential flow, and effective porosity.

(1b)What is the minimum set of parameters needed to characterize the saturated zone so that a realistic conceptual model of the flow system can be developed?

The Panel appeared to be in general agreement that the set of parameters given is likely to provide a reasonably complete characterization of the subsurface flow system in the saturated zone, given the resource constraints that are typical of such studies. However, several Panel members commented on the need for clarification of several points on this issue.

One set of parameters that requires further elaboration involves the specific chemical species for which analyses should be conducted in order to assess "background water quality" (p. 36, ¶5; p.55, ¶5). The term "major ions" is too vague; these species should be listed in a separate table, and the reason(s) for including each one should be specifically provided. In the absence of such justification, the collection of water-quality data of this type (other than pH) can become a "box-checking exercise" that is easily accomplished, but that provides data that are rarely used by the investigator(s) or the reviewers(s) of the study to interpret study results. Although the specific analytes were not provided, a description of "background water quality" should also include analyses for major nutrients (including nitrate, nitrite, ammonia, organic nitrogen, and phosphate).

Piezometers installed at the corners of the field (p. 33) do not always indicate the shape of the water table. This is especially true when the ground water table is at shallow depth (within 1 to 2 m from the land surface). In agricultural fields, it is common to find tile lines that will affect the water table elevation, but whose effects on the water table are not captured by piezometers at the corners. It also possible that the corner piezometers are influenced by nearby ditches or creeks to a considerably greater extent than is the water table in the middle of the site. For example, an increase in the stage of a nearby river might affect only the piezometer close to the river. Furthermore, it is important to note that piezometers measure water pressure and not hydraulic head (p. 35).

To minimize site disturbance, holes drilled for site characterizations be used to install monitoring wells.

(2) Are there methods that can be used to obtain similar information as that determined

from test pits?

For the various reasons given—and despite their acknowledged disadvantages—several Panel members thought that test pits are a valuable way to examine many of the macroscopic characteristics of the soil profile, but, by themselves, provide very little information for describing the abundance, configuration and spatial arrangements of subsurface flow paths. However, by performing an infiltration experiment with an aqueous dye solution (e.g., 1% FD&C #1 blue) before digging the hole and then inspecting the dye pattern in the soil pit, the flow paths may be readily identified. The Australian Soil Survey has experimented successfully with this approach.

One Panel member suggested that the digging of a test pit should be optional and should be included as part of a tiered approach to the characterization of soil structure. If anomalous flow effects are observed in the field, for example, then additional characterization, including the soil pit, may be worth carrying out. None of the information obtained from a test pit is used for modeling purposes. This, combined with the additional cost and disturbance to the site associated with the construction of test pits, represents further justification for making them an optional component of the study design. For extrapolation of the study results, or ranking the site relative to other sites in the use area, other aspects of site characterization obtained from the coring (e.g., texture. OM, soil series description) were considered by the Panel member to be sufficient. Another Panel member maintained that test pits rarely provide significant additional information on soil properties that cannot be obtained through adequate amounts of soil coring and NRCS soil descriptions. The Panel member thus expressed the opinion that the construction of test pits is not an efficient use of study resources, and should be eliminated from the study design.

Yet another opinion was presented that test pits could be used as a way to introduce pesticides into the soil profile at specified depths below the soil surface, in order to improve an understanding of the dynamics of movement in deeper layers. This would be of value to accelerate evaluation of much longer term effects than would be expected from surface application and may aid in extrapolation of data from a typical site, to one of possessing minimal topsoil. However, care would have to be taken to insure some standard interpretation of such data, and to ensure that the resulting observations accurately mimic the behavior of pesticide compounds that enter the vadose zone from the land surface.

MONITORING PLAN DESIGN

(1) How much water should be applied in the initial post-application event? Is the 3-day application window appropriate?

There are limitations and drawbacks for any one way of determining how much water to apply. The major point of the study is to see if the pesticide will be transported under climatic conditions likely to be encountered at the study site, and if so how fast and in what concentration. The amount of water applied must exceed the amount evapotranspired if there is to be any net downward movement. It must also exceed the capacity for storage in the vadose zone. Using an amount based on yearly averages/maximum, crop need or typical practices does not guarantee that enough will be applied to get downward transport. Using application based on transport time for a non-adsorbing tracer ignores the fact that sorption can retard pesticide movement in the soil. Pesticide compounds are usually sorbed to soil solids to a greater extent than the anionic tracers that are typically used, and will therefore move more slowly. In some regions, precipitation is never sufficient to exceed evapotranspiration and soil retention so there is no net downward movement of water. Requiring irrigation to create net downward flow does not appear appropriate in such areas.

A variety of methods have been required by the Agency during the past few years for adding water to plots. The ASD does not state clearly the purpose of irrigation. On one hand there is a general expectation in the document that the tracer will move to ground water within a two-year period, but adding too much water might be too artificial.

The Panel was divided on the upper bound of irrigation rate. One opinion was that the application of water at rates exceeding the maximum recharge rate likely for the site is unwarranted. Instead, the maximum historic yearly net recharge might be the most appropriate amount to apply, since it represents the "worst case" circumstance for the setting of interest.
Alternatively, for irrigated areas, an amount of water equivalent to the maximum anticipated recharge rate under irrigation would probably be most appropriate. Applying water at as high a rate as is required to force the compounds to reach ground water at or above the desired concentration(s) merely shows that such transport is possible; it provides little information on what is likely to occur under conditions of maximal transport in actual practice.

Applying some percentage of normal rainfall plus irrigation (to meet crop ET demands) results in a different return period for different parts of the country. For example, 150% of normal rainfall for the month of May in Iowa is a 1-in-5 year event, while 150% of normal rainfall for May in North Carolina is a 1-in-17 year return period. Thus, the approach yields different levels of vulnerability for the two sites. Additionally, when high levels of irrigation are applied month after month for an entire growing season, the probabilities are compounded, and the effect is to have a very unlikely (low occurrence) recharge situation.

If the rainfall is limited as stated above, and at the same time the tracer must be detected in the groundwater within a two-year period, then this will determine the maximum water-table depth that should be allowed at the study sites(s). Thus the groundwater should be shallow enough so that the tracer can reach the groundwater in detectable concentrations within two years. If the registrant wants to be finished within two years, the registrant can either choose a site with a specific groundwater depth and then add enough water that the tracer will reach the groundwater or fix a rainfall rate and then choose a site where the groundwater is shallow enough.

Thus, the ASD should be revised to emphasize more clearly what the objective of the irrigation is.

(2) How much water should be applied as irrigation after the initial event? How often should it be applied? How is the amount to be determined?

There was confusion about the objectives of irrigation. There are at least three different objectives given in the ASD and presented during the panel discussion: 1) to observe the pesticide behavior that is likely to occur under conditions that mimic what commonly occurs in the setting of interest (p. 42); 2) to minimize photo degradation and; 3) the need to move the tracer through the system in a reasonable length of time.

Overall it was agreed that the uniform requirement that at least two inches of irrigation be applied to the sites is too harsh in some conditions where such rainfall would be unexpected. Furthermore, it should be noted that requiring two inches of rain in a coarse sand on the Florida ridge (field capacity of 5% by volume) is much more harsh than requiring two inches of rainfall on a sandy loam with a field capacity of about 20% by volume. The formula presented by the Agency also may be flawed. It does not take into consideration the application timing. At a minimum, the formula should be based only on the historical rainfall during the application month.

There was agreement that some irrigation or rainfall needs to occur soon after application to minimize photo-degradation. One option recently used by the Agency was to require that at least 1 inch of rainfall or irrigation occur during the first week after application with at least 0.5 inches within the first day of application. As noted previously, Panel members differed whether an additional requirement that the total irrigation plus rainfall in the first month equal 130 percent of normal rainfall is suitable.

Sprinkler irrigation may not be appropriate for sites under drip irrigation, or with tarped beds. Under such circumstances, overhead or sprinkler was deemed to be impractical, impossible, or inconsistent with existing cultural practices.

(3) What is the value of collecting and analyzing soil samples? How many are required? What is the trigger for stopping soil sampling?

The inconsistency in the document regarding the duration of soil sampling needs to be resolved. Soil sampling cannot be terminated after 30 days if non-detects are required in samples at three consecutive monthly intervals. If the purpose of the soil samples is to verify application rates (as stated in the ASD) then filter paper and/or soil samples only need to be collected immediately after each application. If the purpose is to characterize the degradation of parent and metabolites in surface soil, then a different design is needed and at the discretion of the study director, shallow sampling may be continued for the first few months (to obtain a soil dissipation curve, preferably through several dissipation half-lives), or until the concentration of the pesticide and all major degradates in the soil drop below the reporting limit. This potentially provides additional weight-of-evidence that the parent compound has entirely dissipated from the soil, and could support a termination decision if neither the pesticide nor any of its major degradates are detected in the lysimeters or in groundwater.

The timing of sampling throughout the document is fixed with respect to timing of application. For leaching studies, however, rainfall drives the movement of the chemicals. The sampling scheme might therefore be based on effective rainfall amounts, rather than on elapsed time. On the other hand, for field dissipation studies, specifying a fixed time after application for sampling is justified. Rainfall-based sampling requires an on-site sampling crew, greatly increasing the study cost and making it more difficult to have experienced soil sampling personnel available.

Soil samples can provide much insight into the degradation and movement of the compounds under study. Properly collected soil cores collected to the water table, if analyzed with a sufficiently sensitive method, can provide better information than the soil-suction lysimeters. However, soil sampling alone, with no sampling of unsaturated-zone water, may provide an unreliable indication of pesticide movement, since many studies have detected pesticide residues in unsaturated-zone water at depths below the lowest point of detection in soil.

Given the considerable variety of soil solution samplers available, one Panel member thought that deciding beforehand what sampler types might perform best would be difficult. Therefore, installing a variety of different types of samplers at a few locations would probably be better than having many of the same type of sampler at several different locations. This could be accomplished by consulting the extensive existing literature on soil-water sampling techniques to determine the best device(s) to use for this purpose.

It was noted that if soils are collected as part of the study, they should be collected manually to avoid soil compaction caused by tractor-mounted coring devices. Since the most common way to collect soil samples is to use tractor-mounted coring devices and since manual collection requires the use of skilled people to avoid contamination, the elimination of the requirement for all but immediate post-application soil samples seems appropriate. Elimination of this requirement also seems appropriate in light of the poor correlation (p. 44), between pesticide concentrations in soils and in ground water.

The Panel did not develop consensus on the necessary number of samples. One Panel member noted the number of samples could be tied to the requirements laid out in the field dissipation guidelines. A set of 15-20 samples (per depth) composited to three samples should be sufficient to either establish decline or verify residue levels in the soil.

(4) Should a down gradient well be required?

There was no agreement on this issue and the opinion ranged widely depending on the purpose of the down gradient well. The purpose of the PGW study is to determine if the compound leaches to ground water, not what happens after it gets there. The use of down gradient wells might therefore be left to the discretion of the registrant study director.

It was pointed out that installing down gradient wells could become another complex study, requiring the characterization of the regional sub-surface hydrology. One way around the complex characterization would be to use three such wells down-gradient from the plot. There is a good likelihood that one of the three wells would be in the flow path. There was also an opinion offered that down gradient wells might be installed only after the pesticide had been detected in the ground water.

5) When is it acceptable to reuse sites?

Given the resources invested in locating, characterizing, and instrumenting each of these sites, reuse of sites should be practiced to the fullest extent possible. This creates a valuable opportunity to cross-validate models with multiple chemistries and weather years on the same site. However, it is unclear how one might assess the degree to which prior use has modified the physical, chemical or biological characteristics of a given site.

The decision about reuse of sites should be left to the registrant conducting the study, assuming that the proposed tracer is not detected in any soil or water samples from the site. Because current models are generally unable to predict solute concentrations accurately within less than an order of magnitude, if the tracer of interest can be detected at the site, a different tracer--i.e., one that is not detected--should be used. The tracer should be added to, and thus applied with, the pesticide mixture itself (p.43, ¶4). The initial tracer concentration should be high enough for the tracer concentration to be above its detection limit if the original pesticide solution were diluted to the point where the active ingredient concentration would be at its detection limit.

When considering use of a new or reused site, it is important that previously applied products and the test compound(s) of interest should not have any transformation products in common. This can be determined through review of the existing laboratory metabolism data. However, certain chemical classes of pesticides are in very widespread use, and finding a site with no prior use of any pesticides with identical transformation products could be extremely difficult and seriously limit the number of potential PGW sites.

A potential concern (likely a rare occurrence, but possible if compounds with similar metabolic pathways are being tested) is that use of previous product may have resulted in a pre-conditioning the soil microbes, leading to enhanced degradation of the new test compound. This effect is only likely to occur under conditions where there are multiple high rate applications of the first test compound, and if the application of the new test compound. This effect is only likely to occur under conditions where there are multiple rate applications of the first test compound, and if the application of the new test compound is made within a short period of time. If there are two similar compounds being evaluated within a period that may cause concern (<2-3 years), an aerobic soil metabolism study with treated and control soil can be conducted. The need for the metabolism study should consider (1) rate of the compound used in the first PGW study; (2) the number of applications made to the site and; (3) the years since treatment.

<u>MONITORING PLAN IMPLEMENTATION</u>

(1) Is the detail on methods and sample collection adequate? Is it too specific?

Sufficient detail is included for the instrumentation. Most of the basic concepts are presented and adequate citations are provided for additional guidance. The registrant should have the flexibility to employ the most appropriate technology that exists at the time, although new technologies should be encouraged. The Agency should review the appropriateness of these technologies (based on the available literature or, where necessary, additional studies) before recommending their use in a PGW study. As a supplement to the ASD, the Agency should include information documenting the types of equipment and procedures that have been successfully (or unsuccessfully) used in recent studies. The investigation of the suitability of these devices and techniques by the Agency should be sufficiently thorough that the use of any procedure or sampling device included in this list should be acceptable, provided that strict quality-assurance guidelines (e.g., maximum allowable reporting limits for all analytes, minimum analyte recoveries, maximum allowable blank levels, specific reproducibility requirements, safety concerns, etc.) are enforced for all procedures. This approach provides the registrant with some flexibility in their choices of equipment and procedures, while helping to steer them toward the most reliable equipment and methods. As such, it reflects more of a "performance-based" approach than a strictly prescriptive one, and is preferred by the Panel.

The Panel is cognizant of the expense to collect sufficient laboratory and field monitoring data as required by the current guideline. It may be valid to request for more effective and streamlined procedures to reduce the cost of monitoring. In addition, one Panel member commented that the Agency may request from the registrant an estimate for the cost of groundwater clean-up if a certain percent an applied pesticide reaches the groundwater.

The registrants should understand the need to avoid contamination of samples and the resulting unwanted consequences of having residues in samples. However, the very low detection limits used in some studies may make it impossible to prevent contamination, especially just after application. If the latter assumption is made, however, it should be verified by the Agency on the basis of results from previous studies. If this is not possible, then cross-contamination should be deemed unacceptable under any circumstances.

(2) Should the Agency include a list of studies needed to support modeling of the site?

The need for supplementary information is site and chemical specific. Requiring any additional investigations would increase the cost of the study. Sorption and degradation studies of the pesticide and its degradates in surface and subsurface horizons would be useful, if one of the goals of the study is to provide a modeling data set or to develop and test a modeling tool. If this is not a goal of the study, then these studies would provide little value to the study.

Laboratory data are often not representative of what occurs in the field for a variety of reasons including temperature cycling, sustained biological activity, etc. This is especially important in subsoils. Supplemental studies should be required only if the specific conditions encountered at the study site were not encompassed by the previous laboratory studies. In particular, this might be necessary if the previous laboratory study did not examine transformation and sorption in the presence of soils taken from subsurface horizons. The need for supplementary lab studies may be reduced with deep coring during the study to assist with determining degradation rates. Thus, a list of these studies could be provided as guidance, but the conduct should be left to the discretion of the registrant. Such studies could even be started, if necessary, a year or two after the field application. Given that simulation models are supposed to represent our best understanding of the manner in which governing processes interact to control the transport and fate of these compounds, requiring that these data be provided, either from previous studies or by the present investigation, appears reasonable under some circumstances. Data can be sufficiently conclusive that modeling would be simply an exercise. For example, if degradation of the pesticide were to be so rapid that the parent compound would not be detected in ground water, and this were verified through the rapid appearance of the major degradates, modeling might be superfluous. If, at a given site, pesticide movement is affected by preferential flow (funnel or fingered flow in sandy soils) and the model (based on the convective-dispersive equation) cannot accurately predict the study observations, then the model cannot be used to extrapolate the results to other situations. However, if the movement is not affected by preferential flow, these models can be used to explore alternative explanations of the data.

(3) Is the discussion on measures to reduce sampling and analysis justified and useful? Given the significant risks associated with reducing sampling and analysis, is it prudent?

There was general agreement that the best method to reduce the sampling burden would be phased sampling and analysis approach. The Agency should be amenable to reasonable approaches proposed by the registrant.

The use of any measures to reduce sampling burden as noted in the ASD always presents the possibility of compromising the integrity of the study results and most certainly reduces their utility. However, if sufficient supplementary data are available, (as noted in response to the previous question), this risk might be minimized.

If less chemically specific methods, such as immunoassays, are to be used as a screening tool, the registrant could be required to demonstrate that the less specific method is significantly less sensitive to ALL other interfering analytes (degradates AND all other compounds of similar chemical structure) than to the target compound. This approach, however, will necessarily result in a loss of potential information because of the uncertainty regarding the compounds that are actually being detected.

The reliability of using tracers as an indicator for whether pesticide analysis is needed would have to be demonstrated on the basis of a compilation of results from a broad variety of previous studies - another example of the value of examining previous work. If it can be shown that in no case has a target pesticide ever been detected at a greater depth than the maximum depth of detection of its accompanying tracer, then the proposal might be considered reliable. Any exceptions to this pattern, though, would invalidate this approach. In all cases, the ratio of detection limit to initial concentration for the tracer must be equal to or smaller than that for the target pesticide.

Unless evidence in support of either proposal is assembled, measures to reduce sampling and analysis are likely not justified.

(4) Is it valid to store samples pending a termination decision by the Agency? What additional data would be required?

The Panel agreed that it is valid to store samples pending a termination decision by the Agency, if adequate storage stability has been demonstrated. These storage stabilities are likely to vary not only from one analyte to another, but from one matrix to another as well. No single answer is likely to suffice for all analytes and media.

Ideally, the Agency should be able to respond to termination requests within a reasonable time frame to help contain costs for these studies. Final interpretation of the data along with preparation of a final study report could also begin earlier if fast approval for termination of the study is obtained.

(5) Are termination criteria adequate and appropriate?

These criteria assume that only one peak in pesticide concentration would occur, an assumption based on the convective-dispersive approach. Under field conditions, however, pesticide concentrations usually do not follow the convective-dispersive equation, with concentration peaks often appearing during each rainfall event soon after application. The matrix flow peak might occur years later than the initial preferential flow peak. Upward and downward movement of ground water may also create a new peak. Thus, the decrease of pesticide concentration after a peak has to be carefully interpreted. Moreover, the requirement that the peak occur in all monitoring wells might be unnecessarily restrictive. Because of channeling of flow in the subsoil, some wells might never see an increase in concentration. Also, these criteria are appropriate only if they apply to the shallowest well in each cluster. Downward movement at some sites is usually relatively slow. Thus, once it is detected at the shallowest depths, as many as three years may be required for the tracer to reach the deepest well.

The termination criteria appear to be reasonable only if the concentrations of all of the pesticide-derived analytes (parent and degradates) in ground water were consistently less than water-quality limits established for the protection of all non-target organisms (human and non-human). If such limits have not yet been clearly established, then uncertainties regarding the health risk of these concentrations would dictate that monitoring continue until the first two termination criteria listed on p. 59 of the ASD have been satisfied.

The termination of sampling of lysimeters should not necessarily be linked to the termination of sampling of the wells, and that after pesticide residues are no longer detectable in the soil, sampling of lysimeters should no longer be necessary (after two years, bi-monthly or quarterly sampling of wells and lysimeters, it was thought to be sufficient). Many previous studies have demonstrated that detections in unsaturated-zone water and ground water may occur despite an absence of detections in the overlying soils.

SAP Report No. 98-01B, November 19, 1998

REPORT:
FIFRA Scientific Advisory Panel Meeting ,
October 15, 1998, held at the Embassy Suites Hotel,
Arlington, VA

II - A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding:

Review of Proposed Revised Guidance for Conducting Terrestrial Field Dissipation Studies

FOR THE CHAIRPERSON:

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Paul I. Lewis
Designated Federal Official
FIFRA/Scientific Advisory Panel
DATE:____________________

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT
SCIENTIFIC ADVISORY PANEL MEETING

II - A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Review of Proposed Revised Guidance for Conducting Terrestrial Field Dissipation Studies

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The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed its review of the set of scientific issues being considered by the Agency regarding review of proposed revised guidance for conducting terrestrial field dissipation studies. Advance public notice of the meeting was published in the *Federal Register* on September 14, 1998. The review was conducted in an open Panel meeting held in Arlington, VA, on October 15, 1998. The meeting was chaired by **Dr. Ernest E. McConnell** of Toxpath, Inc. **Mr. Paul Lewis,** SAP staff member, served as the Designated Federal Official.

Participants

Members of the Scientific Advisory Panel:

Dr. Jack Barbash, USGS National Water Quality Assessment Program
Dr. Joel Coats, Iowa State University
Dr. Richard DiGiulio, Duke University
Dr. George Hallberg, The Cadmus Group
Dr. Robert Hill, University of Maryland
Dr. Ronald Kendall, Texas Tech University
Dr. Sam Kung, University of Wisconsin
Dr. Fumio Matsumura, University of California at Davis
Dr. Herbert Needleman, University of Pittsburgh
Dr. Jeffrey Novak, USDA Agriculture Research Service
Dr. Christopher Portier, National Institute of Environmental Health Sciences
Dr. Mary Anna Thrall, Colorado State University
Dr. Ali Sadeghi, USDA Agriculture Research Service
Dr. James N. Seiber, University of Nevada
Dr Tammo S. Steenhuis, Cornell University
Dr. Mark Tumeo, Cleveland State University
Dr. Carol Weisskopf, Washington State University
Dr Ian van Wesenbeeck, Dow AgroSciences

Oral statements were received from the following individuals:

Mr. Thomas Gilding (American Crop Protection Association)
Dr. Kimberly Winston (Novartis Crop Protection)
Dr. Russell Jones (Rhone-Poulenc)
Dr. Daniel Dyer (Bayer Corporation)
Mr. Scott Jackson (BASF)
Dr. Aldos Barefoot (DuPont Agricultural Products)

No written statements were received.

Summary of Agency Presentations

Terrestrial field dissipation studies assess the most probable routes and rates of pesticide dissipation under actual use conditions at representative field sites. The studies should be conducted at locations representative of the pesticide use pattern, and a geographic information system (GIS) could be used for targeting field study locations.

Dr. William Effland opened the session with remarks on the goals and objectives of the Agency's presentation. Mr. Nelson Thurman discussed field study design characteristics. Dr. William Effland continued the session commenting on the use of GIS for site selection. Dr. Ian Nicholson (Health Canada) discussed field study methodologies and Dr. Jim Cowles ended the session with a presentation on data reporting, analysis, and interpretation.

Agency Questions and Panel Responses

The Agency presented the following questions to the SAP regarding guidance for terrestrial field dissipation studies. The questions are keyed to the support document entitled *Draft Proposal for a Test Guideline or Guidance Document, Terrestrial Field Dissipation Studies*. Comments on this Agency support document (ASD) and response to questions by the Panel are provided below.

1. Are the proposed revisions for conducting terrestrial field dissipation studies adequate? Can the FIFRA SAP recommend revisions based on the purpose or principle of the test that are not currently discussed in the draft guidance?

<u>Overall quality of Agency support document</u>

In general, the SAP members agreed that the Agency has done a very good job in preparing the revised proposal. In addition, the Panel encourages further stakeholder comment and input as this document evolves. However, the guidance lacks sufficient detail to ensure acceptable uniformity among the resulting studies.

The Agency should clarify the role of field dissipation studies in the registration data collection process, to ensure it is clear how data are to be utilized. Will they include an investigation on transport or a study focused on the rates and mechanisms of degradation in the soil environment? Where in the registration process do the field-dissipation studies come in? The results from these studies could be used to trigger other studies (e.g. prospective ground water studies).

The studies as currently outlined have the potential to become too complex. In an effort to measure everything (all modes of degradation and dissipation), this may result in decreasing confidence of overall study results. One example may be applying the test material to a canopy and then trying to determine soil dissipation in a situation with a highly variable surface input. Also, the number of samples required (3 plots x 20 samples = 60 samples) is probably excessive in terms of effort for only modest gain in statistical power.

The use of the term conceptual model (p.1) to describe the framework of these studies appears inappropriate. The conceptual model of the transport and fate of pesticides—or, for that matter, any chemical species—in the environment should be essentially independent of the chemical structure of the compound in question because the physical, chemical, and biological processes that can potentially govern their environmental behavior are the same. Differences in the environmental behavior of different pesticides arise from variations in the relative importance of the factors shown in the ASD (p.1). However, the concepts and basic processes remain the same, regardless of the compound or the setting. Sources, transport and fate may more accurately convey what is apparently implied by the expression "conceptual model." Studies of this type don't serve to evaluate the validity of this conceptual model so much as to merely refine estimates of the rates at which these various processes occur and, in the case of transformation, identify the specific ways in which the chemical structure may be modified by (bio)chemical reactions *in situ*.
The distinction between 'fate properties and dissipation processes of the pesticide' (p.5) is also unclear.

The requirement that the results be compared with those from previous studies of the same compound is commendable, and should be emphasized more. Furthermore, this discussion should focus on how the results from the present work build on those from previous studies to advance our understanding of the processes controlling the environmental behavior of the target compound(s).

<u>Dissipation</u>

The concept of dissipation as noted in the ASD does not differentiate between the effects of offsite transport to air, surface water or ground water, and (bio)chemical transformation. The distinction between offsite transport and transformation is especially blurred in the definitions for "half-life" and "half-life vs. 50% dissipation time" (p.22). Dissipation includes both degradation and leaching. Although it is not always the case, the degradation products sometimes degrade to harmless products within the soil profile. As a result, the toxicological consequences of "dissipation" (i.e., whether it leads to an increase or a decrease in the overall health risk) are usually uncertain. Leaching is always a potential route of dissipation, and should therefore always be taken into account as a process that can affect the fate of the target compounds. This is especially important because of the stated objective of investigating all major mechanisms of dissipation (p. 14). Therefore, use of the term dissipation should be eliminated in favor of terminology that more precisely describes the fundamental governing processes in question (e.g., offsite transport or [bio]chemical transformation).

Tracers

The application of a tracer should be mandatory, not optional. The tracer should be added to and thus applied with the pesticide mixture itself. The initial tracer concentration should be high enough for the tracer concentration to be well above its detection limit if the original pesticide solution were diluted to the point where the active ingredient concentration would be at its detection limit. The Agency should clearly specify when tracers are needed and limit repetition of such requirements with prospective ground water monitoring studies. Chemical analyses of the tank mixture (p.12) should measure the concentrations of the active ingredient(s), degradates (to see if any reaction has taken place prior to application), the tracer and any adjuvants representing a certain minimum percentage of the original formulation (e.g., 1% by mass).

Mass Balance and Mass Accounting

The Panel provided several comments concerning mass balance. The concept/conceptual model should be approached as a mass balance. However, this is challenging because as described, the field study does not address many major pathways, limiting utilization of a mass balance approach. The data collected should be information that can be used in model(s) that can help to assess various loss routes to understand the data.

Mass accounting, not mass balance--for the tracer, as well as the applied pesticide and adjuvants--should be considered mandatory for all field studies. The Panel members generally agreed that mass-balancing of pesticides under field conditions is not practical because of the complexity of differentiating quantitatively the various component of pesticide loss pathways. However, mass-accounting for pesticide dissipation components in field, to some level of acceptance, is practical and useful.

The term mass accounting should be interpreted to mean the effort to estimate, as precisely as possible, the proportion of the total mass of applied compound (tracer, pesticide and adjuvants) that 'dissipates' from the site of application through leaching, runoff, volatilization, transformation and plant uptake. It should not be confused with mass balance, which represents a complete accounting for 100% of the applied compound in terms of all of these processes.

Computation of a mass accounting should compensate for the fact that when a pesticide undergoes transformation *in situ*, the chemical structure of the compound, and, most likely, its molecular weight, will change. Although in most cases this leads to a decrease in molecular weight, for compounds such as the acetanilides, some transformation pathways might actually lead to an increase in the molecular weight. Consequently, for any compound (pesticide or adjuvant) that undergoes transformation, a more appropriate approach would be to track all concentrations on a molar, rather than a mass-per-unit volume basis. This is, admittedly, a minor point, but it would lead to more precise thinking in terms of tracking the ultimate fate of the applied compounds.

The use of a tiered, modular, or assessment index approach will all involve the concept of scaling. Studies of specific mechanisms of pesticide "dissipation" can be effectively used to simulate worst case scenarios of pesticide dissipation or loss, but because of scaling issues, those results can not be quantitatively used to estimate field or watershed scale dissipation and loss. The mass balance or mass accounting concepts can be used within the individual component studies, but again because of scaling issues, the use of the same data can not be directly used in a quantitative manner to estimate field-based mass balances or mass accounting. One Panel member disagreed with this point, maintaining that the results from properly designed laboratory studies should be directly applicable to understanding the results from well-designed field investigations, regardless of scale.

Even though mass accounting is addressed, no target values or acceptable values are provided. This raised several questions to the Panel. What does "unexpectedly low" mass accounting mean? To what extent must the registrant go to attempt to attain an acceptable mass accounting? Over what time period does the mass accounting apply? Routine chromatographic methods for measuring residues of a non-radioactive pesticide will not provide for a very high percentage of recovery. Radiotracers will allow for better accounting of the applied mass of the pesticide.

Panel members differed on the use of radiolabeled tracers to account for the pesticide. One Panel member stated that the use of radiolabeled substances in field dissipation studies should be avoided. Research has shown that labeled pesticides can be incorporated into the soil organic matter fraction and remain detectable for several years. Detection of background radiolabeled compounds, if uncorrected, introduces error in data collection and may compromise the experiment (p. 3) . The use of radiotracers will impair the ability to track the chemical changes that take place as the pesticide(s) of interest age and move through the soil.

However, another Panel member commented that radiolabeled studies provide valuable information on the degradation and formation of metabolites and often result in enhanced delectability. Radiolabeled studies are also very useful for pipe lysimeter studies.

Multiple Applications

The approach of increasing application rates above the maximum rate allowed on the label in order to accommodate unacceptably high method detection limits is inadequate, as well as inconsistent with the ASD (p.8). Instead of increasing application rates, more effort should be invested in lowering the method detection limits.

Application of some pesticides in consecutive years can lead to enhanced microbial degradation due to selection for bacteria that can catabolize the pesticide as a nutrient or energy source. Under this scenario, persistence is shorter for each successive application, but this should not be an environmental problem. However, the spectrum of transformation products formed may possibly be different than under a first-time application scenario.

Dissipation Rates

The Panel did not support the use of multiple application to measure dissipation rates. Measuring dissipation rates from multiple applications will provide results that are ambiguous at best, and uninterpretable at worst, if transformation products are being monitored, as they should. This approach could also lead to acclimation of the soil microorganisms, further complicating the interpretation of the results.

Multiple applications of a pesticide may confound the determination of a half-life or DT_{50}. One application is suitable for a good soil dissipation curve followed by utilizing a model to determine the effect of superimposing several applications over a growing season.

Leaching

The extent of leaching cannot be fully determined if only soil, and no ground water, is examined, primarily because of the possibility that compounds carried in unsaturated-zone water may bypass the soil and move directly to the ground water below. This is especially important because the compound used for the GIS example by the Agency was expected to leach. It is not clear that "lateral flow" is a recognized phenomenon. Water may travel laterally along near-horizontal discontinuities in the subsurface and should be considered as leaching by the Agency.

Laboratory versus field studies

Several Panel members emphasized that field-based conditions could not easily be duplicated in a laboratory situation. Laboratory results should be focused for the design of field studies. The necessity for conducting a field study should be for the situations where the performance and behavior of a chemical that has already been studied in the laboratory is different under real field conditions. Although laboratory studies can be an integral component to help evaluate field dissipation of pesticides, they can not replace the physical, biological, and ecosystem processes observed under field conditions. Column studies can be used as an assessment component of a larger study to help evaluate the relative risks of pesticide applications. Quantitative losses observed from the base of a leaching column or quantitative runoff losses from a small plot rainfall simulation study can not be directly expanded to estimate large scale field losses. The results from small scale component studies are a cost effective and scientifically efficient means to evaluate relative rates of pesticide dissipation. The scientific community continues to struggle with methods to expand small scale experimental results to larger field and watershed scales.

Although some Panel members argued that the Agency should emphasize conceptual modeling based on laboratory columns, these laboratory columns are disturbed soil columns without structure and are extremely poor for predicting leaching potential. However, several Panel members thought that the methods used in the field study itself are themselves unable to detect leaching, and are thus unable to document the movement of pesticides to groundwater. This is exemplified by the statements on pages 15 and 16 of the ASD "If the overall mass accounting is unexpectedly low, major route(s) of dissipation were possibly not adequately addressed in your field study design". One of the pathways not considered in the dissipation study is the leaching of the pesticides below 1 m depth. A simple mass balance shows that for pesticides that are toxic in the ppb range, a one percent leaching loss of the amount applied can cause the drinking water standard to be exceeded for a year or longer. A mass balance difference of one percent is almost impossible to detect and certainly does not constitute an "unexpectedly low mass balance". Although the statement might be true for dissipation studies, it cannot be argued that the pesticide is environmentally safe if the mass balance is met. Thus, the Agency should develop guidance for an acceptable mass balance level.

Site topography and surface crop residue concentrations

Two additional features that should be listed under factors to consider for site selection include site topography and surface crop residue cover. A soil's topographic position will influence organic carbon levels, and thus the quantity of pesticide sorbed and the pesticide leaching potential. Additionally, the use of conservation tillage to till soil is increasing. In conservation tillage, crop residues remain on the surface and will intercept foliar applied pesticides. Pesticides intercepted by plant residue will be washed off easily by rainfall, and can move with surface runoff (p. 4).

Depth of measurement

The revised draft should specify at which depth the soil water and temperature conditions will be measured. One Panel member commented that measurements at a soil depth of 15 and/or 30 cm can be used since this is generally regarded as the "main zone" for soil organic carbon mineralization and microbial mediated pesticide transformation processes (p. 9). There should also be an indication as to the appropriate depth to record soil temperature.

In contrast however, another Panel member thought that rather than basing the depth of measurement on some semi-arbitrary decision about where the "main zone" for microbial activity might be, the depth of measurement of soil properties should be that at which the phenomenon of interest is taking place. Thus, if the measurements are to be tied to an estimate of the "dissipation half-life", then they should be made at the depth from which the soil samples are taken for estimating this parameter. Otherwise, the measurements of temperature and water content cannot be tied to the half-life estimate.

Soil core analysis

Some of the soil core analysis can be much more effectively done with appropriate tension pan lysimeter. A soil profile description in itself cannot be used for predicting the pesticide leaching but a soil profile description with dyes might give information about flow path.

There should be a greater emphasis on describing procedures for filling core holes in test plots. Over the field study, there will be many core holes that will require repacking. If not repacked properly, the probability of contamination is high due to treated soil falling down the core shaft. This will skew the data and compromise the experiment. Soil core holes should be repacked with soil obtained from a similar depth from a control plot. Ideally, the soil in the core shaft should be repacked to the same bulk density as the initial soil. After plugging, there will some soil subsidence. Periodically, the old core holes should be repacked with new soil to fill up the small craters. Spreading excess untreated soil around the test plot should be avoided because of the possibility of dilution, especially for pesticides applied at ultra-low application rates (p. 11).

However, other Panel members stated that repacking of soil core evacuations with soil from the same layer and at the same density as the undisturbed soil does not seem practically possible. A sand:bentonite mixture (e.g. 6:1, 7:1), which would not settle, could be easily applied and would help insure that the same area was not sampled at a future date.

There will be too many soil core samples taken in the small test plots (2 m^2). The ASD has cited a few references that recommend collection of between 10 and 15 samples down to 100 cm. This implies that upwards of 120 (3 cm by 100 cm) soil cores will be collected over a year (12 sampling periods). This is simply too many soil cores for a small volume of soil. Even after sufficient soil repacking, the normal soil hydraulic properties (infiltration, permeability) probably will be drastically altered (p. 13). Thus, one Panel member concluded that due to the bore holes, the soil test plot will eventually have the hydraulic properties of Swiss cheese.

<u>Other considerations</u>

The ASD states that bare study plots must “be maintained plant-free”, without any guidance as to acceptable means of accomplishing that such as with cultivation or application of herbicides. In addition, how plant-free should they be and for how long?

Air sampling should be performed and additional guidance for registrants would be useful, such as basing the decision on physical properties, laboratory data, proposed application method and expected environmental conditions at application time.

Although the procedures outlined entail a comprehensive methodology, it is somewhat disturbing that a zero knowledge base is inherently assumed with all compounds being treated the same. The opinion was expressed that expertise is likely to exist to create a pesticide dissipation / loss risk assessment index for the evaluation of potential compounds. Highly water soluble and minimally sorbed compounds would be expected to have different behavioral and assessment criteria than relatively insoluble and tightly bound pesticides. The development of a weighted index based on pesticide characteristics, soil and crop parameters, and climate interactions seems within grasp to allow a risk assessment class to be applied to potential compounds being evaluated as pesticides. The index could also have a tree structure and require more extensive assessment evaluation for likely potential avenues of dissipation and loss. Indexing systems of this type have a relatively long history, dating back to at least the mid-1980s. One Panel member commented, however, that none of these systems has yet been proven to provide accurate predictions of the likelihood of detecting specific pesticides or their transformation products in ground water. The use of a system of this type should therefore be contingent upon a clear demonstration that its predictions are reliable.

The Panel also recommends the following revisions: 1) measurements of pesticide application uniformity through placement of adsorbent surface membranes; 2) soil water content measurements with depth to allow the calculation of water flux. Water content measurements alone do not necessarily allow the determination of water balance; 3) soil sampling strategies that are tied to precipitation or water application events; 4) methods to evaluate the potential for preferential transport of solutes; 5) investigation of the effects that composite sampling will have on masking preferential movement of solutes; 6) recording of the temperature and, wherever possible, pH at which all parameter measurements are mad (pp. 3, 15); 7) listing of published methods for sampling runoff, air, etc. since the guidance within this document is very vague; 8) a modular or tiered approach to determine priorities among different components of the study; (9) chemical analyses of the tank mixture should measure the concentration of the active ingredient(s), the tracer and any adjuvants representing a certain minimum percentage of the original formulation (e.g., 1% by mass) and; (10) the document should refer to the appropriate test guidelines for pesticides which are applied to field water, such as flooded rice fields.

2. What additional suggestions and corrections are required to complete this guidance document before it is submitted to the Organization for Economic Cooperation and Development (OECD)?

Some of the Panel members concluded that the document reflects current thinking and that it should be regarded as a temporary set of guidelines to be used until more environmentally appropriate and cost effective guidelines are developed. Panel members and Agency staff agreed that the guideline is not ready for “prime time” and that the OECD position will take several years to evolve, through joint U.S. and Canadian effort.

3. Does the FIFRA Scientific Advisory Panel have any recommendations on the number of field studies required to statistically evaluate field dissipation of pesticides?

Panel members differed in their response to this question. The number of field sites needed will depend upon a few variables. First, the number and acreage of crops which the pesticide will be applied should provide a perspective for the number of field sites. Secondly, numerous field sites may be necessary if the pesticide behavior varies with changes in soil properties. It is plausible that several field trials will need to be conducted in soils formed in various parent materials. For instance, if the pesticide is labeled for use in the Midwest, then soils formed from glacial till, loess, or fluvial material could be used. If the pesticide is labeled for crops in the southeast, then soils formed in the Piedmont, and Coastal Plain may be selected.

Statistical considerations are important factors to address the number of field studies. It is statistically prudent to perform experiments with at least three data points. This way if a high and a low value is present in the data pool, the third data points usually balances out the variation. Panel members differed whether at least tree data points are necessary for most statistical programs. In addition, the number of studies required to represent soil dissipation and all the other dissipation mechanisms in one study in a statistically valid way is likely not within the realm of possibility (impractical and expensive). Thus, the notion of a statistical treatment of data between sites is likely not realistic.

A review of the experience, procedure and variability in developing guidelines for field studies of terrestrial, aquatic, and ecological effects should be conducted. A retrospective of the results from past studies would help. Within this, the number of sites will need to be tailored to the compound and the range (spatially, related to crops and regions) of use. Climate and soil/environmental variables will affect the range and number of sites needed.

It was noted that at least two field sites would seem appropriate, although there can be a tremendous range of variability encompassed with only two sites. The potential for dissipation /loss is inherently a function of compound properties and site characteristics. Since the ultimate goal of the assessment is to evaluate potential detrimental effects on the environment, sites possessing characteristics that would result in worst case scenarios for each compound seem appropriate. As an example, sandy soils with low organic matter contents and high leaching capacities would seem to be a logical worst case scenario site for compounds that are highly water soluble and minimally sorbed.

However, some Panel members commented that this question cannot be answered with much rigor because it is so dependent upon the parameter, site, environmental conditions, pesticide of interest, use pattern, relevant geographical factors, and climate. Correlation of field data with laboratory data, and subsequent probabilistic modeling (to account for variability and uncertainty) is probably the most effective way to extrapolate the results of a limited number field dissipation studies. Perhaps more specific guidelines could be developed, based on the number of hectares on which the pesticide would be used.

4. Would the FIFRA Scientific Advisory Panel recommend conducting additional field studies to evaluate field crop residues, surface runoff, and terrestrial effects and exposure? What, if any, precautions should be taken if other studies are conducted at the same time as a field dissipation study to ensure that the study results meet each study's objective and are not compromised?

There are clear economies, efficiencies, and improvements that could result from combining studies. To evaluate the possibilities, the objectives of the studies should be more clearly and explicitly defined. Some are more obviously compatible with the regulatory process and objective than others. Some combination (e.g., dissipation with crop residue) would seem very logical to help account for a more complete mass balance (for studies in which mass balances will be examined). Given the timing in the regulatory process and the study objectives, it may be difficult to combine the field dissipation studies with runoff or leaching/prospective ground water monitoring studies.

It is not clear if bound residues or strongly sorbed residues are included. If so, are they considered as part of the dissipation or part of the persistence (including retention and carry over)? Are they considered to be biologically, chemically, or physically unavailable? Are they assumed to consist of parent compound? How are they to be presented and interpreted by the registrant? Can they be accurately assessed quantitatively when non-radiolabeled pesticide is used for these studies? Should bound residues be evaluated only in lab studies? Mass balance or mass accounting will be extremely difficult without considering and measuring the bound residues. The use of a radiotracer which would at least allow quantitative determination of the bound residues. The characterization of the bound residues is still difficult although progress is being made. It should also be noted in this context that the precise chemical and physical nature of these so-called bound residues is still unclear. In particular, it is usually unclear whether they consist of the parent compound (or degradate) chemically bound to organic matter or some other soil surface, or just sorbed or sequestered within internal pores in the soil. Thus, if bound residues were to become an entity of interest to these studies, it should be established--to the extent possible--whether the difficulty of their extraction from the soil arises from their actually being chemically bound to the soil, or from their being merely less accessible because they reside in zones of "immobile water" inside internal pores.

An obvious advantage on conducting several studies simultaneously on the same field site would be the more efficient use of resources (money, space, time). In addition, there would be cases in which the data from one type of study could help the understanding of data from a different, coincident study. For example, field dissipation data could be very helpful in interpreting data from terrestrial effects and exposure studies. Likewise, surface runoff studies could fit well with field dissipation studies. However, there are numerous precautions that must be addressed under a situation of coincident studies. Primarily, they center on making sure that the sampling (and data collection in general) for a given study does not disrupt the integrity of the plot for use in the other studies. Very close coordination of scientists conducting the various studies would be extremely important so as to prevent jeopardizing the results.

The Panel recommended several factors to consider when conducting both field residue/runoff and field dissipation studies:

- Similarity of soils at each site

- Topographical variations between sites
- Matching the typical surface percent residue cover remaining after tillage with values typical in the ecoregion
- Tillage and crop rotation histories
- Previous pesticide application history
- Minimizing runoff containing pesticides from contacting field used for dissipation study (if tested side by side)
- Increase in soil macropores by conservation tillage can expedite pesticide leaching through soil

It is not always practical to combine processes (e.g. a dissipation study on high slopes and/or runoff study on flat terrain), it should be based upon the objective of the study. If the main objective is field dissipation, then if there is runoff, that should be considered as well, but do not design field dissipation on high slope sites.

The guidance document should be replaced with the applicable sections from the prospective ground water monitoring study guidelines, after including some of the changes suggested by the Panel for that document. While the latter lacks some of the focus of this document on foliar applications and air sampling, the two sets of guidelines could easily be combined into a single document that improves upon them both. The specific distinction between the terrestrial field dissipation studies and the prospective ground water monitoring studies (p.2, #6) is unclear, particularly in light of the pronounced similarity in the variables used to characterize the study sites for the two types of investigation. Indeed, the design of the terrestrial field dissipation studies appears to be largely a subset of that for the prospective ground water monitoring studies, except for the sampling of air and foliage required for the field dissipation studies. At a minimum, therefore, the methods and types of data used for characterizing the study sites that overlap between the two documents (e.g., characterization of soils, climatic regime, etc.) should be identical for the two types of investigation. In general, the guidelines for site characterization for the prospective ground water studies would be preferred, since they are provided in more systematic detail. However, the guidelines for accounting for the effects of variations in formulation (pp. 7-8) are more extensive for the terrestrial field dissipation studies and should thus be applied to the prospective ground water design. Indeed, serious consideration should be given to having an independent party—i.e., other than those who produced either of the two documents—combine the two types of studies into a single design.

It might be appropriate to combine this document with the guidance for the prospective ground water monitoring studies, then add in a similar surface-water component to estimate the rates of transport and transformation in runoff and stationary water bodies (i.e., lakes, ponds, and estuaries) and include an expanded atmospheric component to estimate offsite transport in air and precipitation. Study results will not be compromised as long as a sufficient level of detail is provided in the guidance for study design. This level of detail is more closely approximated by the guidelines for the prospective ground water monitoring studies than by the guidance for the terrestrial field dissipation studies.

Additional field studies may be appropriate and warranted, depending on the characteristics of the compound under consideration and likely potential avenues for dissipation or loss. If compounds could be separated into a series of classes based on known chemical and physical characteristics, then a more extensive assessment into the likely pathways of dissipation or loss could occur. As an example, compounds with a high potential for runoff losses, either through solution in runoff water or sediment-associated loss, might be subjected to a series or rainfall simulation assessments and not depend on natural rainfall events. Soil and water loss evaluations based on natural rainfall occurrence and events usually take 10 to 25 years and are often used in justifications for using simulated rainfall. Chemicals that are highly soluble in water are rapidly leached into the soil where they are not subject to surface loss. Only when a significant runoff event occurs soon after application of the compound will surface losses of soluble compounds be excessive. A critical event is defined as one that occurs within 2 weeks of pesticide application, involves at least one cm of rain, and results in runoff volume which is 50% or more of the precipitation. A catastrophic rainfall event is defined as one that has surface losses of 2% or more of the applied pesticide.

The occurrence of a severe rainfall event can result in increased chemical losses of any surface-applied pesticide. The loss of pesticides formulated as wettable powders could be typically 3 times the long-term anticipated loss of 2 to 5% if a critical event was the first rainfall occurrence. Most pesticides lost via the soil surface are lost in the aqueous phase of surface flow. Early rainfall events shortly following application can also result in soluble compounds by-passing the adsorptive upper layers of the soil profile and being transported by preferential flow to lower depths. The use of a weighted pesticide risk assessment index could be used to determine additional assessment procedures based on potential avenues of dissipation or loss. However, as noted earlier, no such indices should be used for this purpose unless they have been demonstrated to provide reliable predictions of the relative risk of environmental contamination by the compound(s) of interest.

The terrestrial field studies document should make it clear how/when to conduct volatility, runoff and other special studies in conjunction with terrestrial dissipation. The document should specify whether and how the objectives for volatility, runoff, degradation and other aspects of field behavior could be met in a single terrestrial field study design.

5. Is the Geographic Information System (GIS) model used to target suitable locations for conducting field studies applicable? Why or why not? Can the FIFRA Scientific Advisory Panel identify further refinements to the proposed GIS model that would increase its applicability?

The prototype presented is an excellent example of the strengths of a GIS tool. Multiple layers of data from numerous sources can be brought together and analyzed in a coherent and systematic way. This makes the GIS-based tool proposed by the EPA and Health Canada a good way to help pinpoint field study sites as well as to extrapolate data/results from these sites. It was noted by several Panel members that the tool might be useful, and perhaps more appropriate, for the selection of sites and interpretation of data from the proposed prospective ground water monitoring studies.

The Panel concluded that the prototype GIS-system presented could be a very useful tool to help locate suitable sites. However, it is important to address the issue of whether this tool will be specified as the required tool for site selection, which the Panel does not believe is appropriate, or if it represents one possible approach the Agency would accept, which may be acceptable.

The Panel questioned whether GIS would be used as the scientific support for identification and selection of the location for field dissipation studies or conversely, will it be a conceptual prototype approach that will be required or recommended for use? There are many resource constraints and intellectual property issues that must be faced if the EPA and Health Canada intend to develop and distribute the system as the tool for registrants to use, and the Panel raised some concern about this possibility. Because of the resource constraints that would most likely be faced by both EPA and Health Canada, attempting to develop, distribute, and support a GIS-tool for use by registrants would likely result in a partially developed tool with little to no utility. These concerns are further compounded by the differences in U.S. and Canadian law concerning intellectual property developed in government agencies, the differing scales of data available and the necessity to update and maintain separate databases which may have significant regulatory importance outside of the case at hand.

Overall, it would be best if the EPA and Health Canada choose to move forward with this system and that it be developed as an example of one tool that could be used in site selection. It would most likely be more effective to let the registrants and the market develop the tool, keep it up to date, and bring in innovative approaches. It is possible that larger registrants are already developing such tools related to precision agriculture as well as associated marketing programs. However the tool is developed, there should be close coordination with other offices within EPA as well as other federal agencies in the U.S. and Canada, industry and academia.

There are several issues that need to be addressed about the proposed approach. First, the geospatial scales used in the database vary considerably between the United States (1:250,000) and Canada (1:1,000,000). This variation makes use of the system problematic at best. Additionally, there are much better potential databases within the U.S., with even finer scales. One potential solution to this problem is to establish a base map for the entire area at a consistent scale (the largest) and then layer finer scales into the system for those areas for which finer scale data are available. This would take a considerable amount of programming and resources, but would produce a highly usable tool that could address the large variation in data-scales currently encompassed by the system.

Second, the Agency should do whatever is possible to maximize the accuracy and reliability of the input data, rather than focusing too much on the software. For example, collection of data on non-agricultural, as well as agricultural pesticide use (i.e., pesticide use on turf, forests, gardens, rights-of-way, buildings, residences, aquatic weeds, etc.) to estimate the amounts of pesticides applied to the land should be pursued. Data on adjuvant application rates should also be included.

Third, collection of data on non-agricultural, as well as agricultural pesticide use (i.e., pesticide use on turf, forests, gardens, rights-of-way, buildings, residences, aquatic weeds, etc.) should be performed to estimate the amounts of pesticides applied to the land. Data on adjuvant application rates should also be included.

There are also some concerns that the use of the tool could produce selections which are not optimal. Because the GIS-tool does not consider factors such as access to the potential field sites and distance from cooperators, use of the tool may force selection of sites in areas not practical from a cooperator point of view, especially if required in guidance as a selection support tool. Finally, the required use of such a potentially complicated software tool may result in a detailed site selection process that will drive up the cost of the study.

Numerous other databases are available or will soon become available that should be considered by the Agency. Examples of available data sets which would be valuable include: soil conditions (permeability, etc); groundwater quantity, quality and depth; local flora and fauna; land-use besides agriculture; and information on endangered species. These databases will be at varying spatial scales, and will require extensive resources and time to add to the system and maintain. This can be a very useful tool to help locate suitable sites, as well as to extrapolate data/results from these sites. There are various concerns with data scale and data sources that should be incorporated. In developing the prototype, efforts and information should be coordinated with other offices within EPA as well as other agencies.

However, output from any GIS model is only as good as its input data. Thus, the only way the reliability of this model can be evaluated is to check its predictions against actual field observations. If the various site characteristics predicted by the model are actually encountered in randomly-selected locations across North America with an acceptably high degree of accuracy, then this model is a valuable tool. Otherwise, it is not. Even though the Agency should consider available databases, the Agency should focus on maximizing the accuracy and reliability of the input data, rather than focusing too much on the software.

GIS-based decision support models may be useful tools to assist in identification of appropriate regions for field studies. This approach may allow for easier location of similar (or dissimilar) or comparable sites for field dissipation studies. However, there are some limitations at a fine scale, such that specific sites will still need to be selected to some degree on the basis of local or site-specific information on soil, topography, drainage, and vegetation. Overall, GIS certainly seems to be a tool that could serve a valuable role in the site-selection process.

The use of GIS to identify analogous geographical areas for potential pesticide use and assessment seems appropriate for eco-region selection although it should be noted that limitations exist. A common problem with the use of GIS for environmental or agriculture analogy assessments is the level of information included in the GIS polygon layers. These scale problems with respect to soil level information are particularly acute with soil survey map level information, which is usually the most detailed information available, indicating ranges of physical and chemical property information. The Agency noted that these soil variability and map scale issues prevent the precise identification of field location sites for evaluation and that the GIS system is not intended for that purpose. The use of a GIS system to evaluate range of applicability in an eco-region approach would seem very useful.

6. Based on the current proposed revisions to replication of field studies, can the FIFRA Scientific Advisory Panel describe appropriate methods (e.g., analysis of variance) for determining statistically significant differences in field study results?

A single answer to this question cannot be provided easily. The particular statistical test used will depend upon the specific parameter of interest and the number and statistical distribution of its measured values. Standard statistical techniques, described in most basic statistics textbooks, would probably suffice.

ANOVA seems to be the appropriate method for statistical analysis of significant differences in data obtained from field dissipation studies. Limitations on the statistical interpretation of results are nearly always most dependent on the sampling design and techniques.

Techniques exist that utilize combined ANOVA procedures that may be applied over locations or time if appropriate conditions are met. The potential also exists to apply probability density functions to the results of field studies to determine the probability for dissipation or loss in terms of statistical confidence intervals. Loss assessment ratios could then be developed for different soil and climatic scenarios.

Generally, one must determine if the data set was obtained from a population that is normally distributed and has equal variances. There are a few normality tests available on computer statistical programs (e.g. Kolmogorov-Smirnov distribution, D'Agostino D test). If the data set is found to fit these criteria, then a parametric test may be used to test for significant differences between mean values (ANOVA, t-test, least significant difference). When these assumptions are not valid and distributions fail to produce appropriate results, nonparametric or distribution-free procedures are valid alternatives. Nonparametric procedures thus have a broader range of applicability because they require fewer assumptions. An example of a popular nonparemetric test available on computer software packages includes the Mann-Whitney Rank sum test (also referred to as the Wilcoxon Rank Sum test).