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

A Set of Scientific Issues Being Considered by the Agency in Connection with Estimating Drinking Water Exposure as a Component of the Dietary Risk Assessment

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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 in connection with estimating drinking water exposure as a component of the dietary risk assessment. The review was conducted in an open meeting held in Arlington, Virginia, on December 10, 1997. The meeting was chaired by Dr. Ernest E. McConnell. Other Panel members present were: Dr. David Baker (Heidelberg College); Dr. Charles Capen (The Ohio State University); Mr. Brian Cohen (Environmental Working Group); Dr. Jerry Hatfield (U.S. Department of Agriculture); Dr. Paul Hendley (Zeneca AG); Dr. Allen Isensee (U.S. Department of Agriculture); Dr. Dennis Laskowski (DOWELANCO); Dr. Martin Locke (U.S. Department of Agriculture); Dr. Edo Pellizzari (Research Triangle Institute); Dr. Howard Rockette (University of Pittsburgh); Dr. Ali Sadeghi (U.S. Department of Agriculture); and Dr. Mary Anna Thrall (Colorado State University).

Public notice of the meeting was published in the Federal Register on November 4, 1997.

Oral statements were received from the following:

Stuart Z. Cohen, Ph.D., Environmental & Turf Services, Inc.
Peter N. Coody, Ph.D., Pharmacological/ Toxicological Research Lab (PTRL) East
Raymond J. Layton, Ph.D., DuPont Corporation, representing the American Crop Protection Association
Barbara J. Petersen, Ph.D., Novigen Sciences, Inc.

Review of Interim Methods For Estimating Exposure To Pesticide Contaminated Drinking Water With Responses/ Comments From The Scientific Advisory Panel

Background:

Each year, EPA's Office of Pesticide Programs (OPP) assesses the potential risks of 50-100 pesticides to humans associated with the pesticide contamination of drinking water. Some of the pesticides are currently registered candidates for reregistration and some are candidates for new registration.

In attempting to perform drinking water exposure assessments, OPP is faced with three major problems:

(1) Certain pesticides pose a greater risk of water contamination than others, and using sophisticated models and analyses to develop estimates of water concentrations for use in risk assessments is resource intensive. Consequently, OPP needs to develop a tiered approach for generating drinking water risk assessments which is capable within the lower tiers of accurately screening (and eliminating from further assessment) pesticides that pose little or no risk. The lower screening tiers would be based on screening model estimates of pesticide concentrations in ground and surface water source drinking water that are highly conservative and/or monitoring data for reasonable worst-case sites with respect to leaching and/or runoff. The higher tiers would be based on more sophisticated and accurate computer model estimates of pesticide concentrations and/or monitoring data covering more extensive use areas.

(2) OPP must estimate pesticide concentrations in both surface water and groundwater. Until the recent development of the Screening Concentration In GROund Water (SCI-GROW) model, OPP had no way of estimating pesticide concentrations in ground water. Current methods for estimating pesticide concentrations in surface water involve modeling edge-of-the-field ponds which are not typically used for drinking water. Such estimates are appropriate for screening ecological concerns, but these may be inappropriately conservative for drinking water assessments -- even for preliminary screens within lower tiers of a risk assessment. OPP is currently developing and modifying existing screening models and needs to develop the capability of using more advanced basin scale models for the higher tiers of risk assessment. There is another primary factor contributing to the overly conservative nature of estimated pesticide concentrations in an edge-of-the-field pond for use in drinking water screens. Most surface source drinking water originates in flowing water where it is subject to dilution from flow from untreated areas; such water often ends up in a drinking water reservoir with a long hydrologic residence time. OPP is currently

developing a conceptual screening model for surface source drinking water that will take into account flowing water, dilution from runoff water, and reservoirs.

3) The available monitoring data for pesticides in raw and finished drinking water are limited but should not be dismissed. However, the available data on pesticides in raw natural water is gradually increasing due primarily to the efforts of a small numbers of states and through the National Water Quality Assessment (NAWQA) Program and other U.S. Geological Survey (USGS) monitoring projects. OPP needs to develop methods for using monitoring data on pesticides in raw natural water and in raw and finished drinking water to help generate risk assessments. It also needs to develop criteria for requiring drinking water monitoring data from the registrants and SOPs for collecting such data.

OPP has identified both short term/interim and long term goals for addressing these problems. The longer term goals of OPP include the development of basin scale modeling capabilities, criteria for requiring pesticide monitoring of drinking water by registrants, and Standard Operating Procedures (SOPs) for collecting such data. The short term/interim goals are the focus of this meeting of the SAP. Those goals are to develop and/or modify existing screening models to improve their accuracy, and, to develop methods for using available monitoring data to help generate drinking water exposure and risk assessments.

OPP's Interim Drinking Water Dietary Exposure Assessment Approach

OPP is required by the Food Quality Protection Act of 1996 (FQPA) to factor drinking water routinely into the dietary exposure assessment for purposes of tolerance decision making. This requirement subsequently has forced OPP to develop an interim approach for estimating pesticide concentrations in drinking water. FQPA calls for examining multimedia consideration in exposure assessments. Section 118 requires that drinking water to be included in the risk characterization. As such the Agency has been compiling and evaluating existing methodologies and tools for aquatic exposure assessment and ground water protection for use as interim approaches. OPP’s interim approach, including refinements, assumes the following form:

Step 1: Formulate environmental fate and transport assessment; evaluate use patterns.

Step 2: Conduct screening level modeling (Tier 1) with screening models SCI-GROW and GENEEC (GENeric Estimated Environmental Concentrations); A proposed new flowing water/reservoir module was proposed for incorporation into GENEEC.

Step 3: Compare model predictions with levels of concern, adjusting surface water (but not ground water) predictions with Crop Area Factors (CAFs); determine the need for refined modeling; carry out a preliminary review of monitoring data (ground truthing).

Step 4: Conduct refined modeling for surface water [Tier 2 via Pesticide Root Zone Model/ Exposure Analysis Modeling System (PRZM/EXAMS) - - no tier 2 modeling exists for ground water]; carry out comprehensive assessment of monitoring data.

Step 5: Compare refined modeling and monitoring data with levels of concern.

OPP indicated this approach depends on sound scientific judgment in balancing the interpretation of results from conservative models with reliable and appropriate monitoring data. OPP asked the Panel for guidance on the implementation and refinement of the interim drinking water exposure assessment process. A general question to be addressed by the Panel is whether the proposed approach at the Tier 1 screening level is adequately conservative.

The Panel also understands from discussions during the meeting that drinking water exposure methodology is being pursued by the International Life Sciences Institute (ILSI) and that OPP will work new methodology emanating from this body of experts into its drinking water exposure assessment approach as the methodology becomes available.

In addition, there are longer-term projects underway including the development/ refinement of watershed models and liaison with USGS and NAWQA programs.

Screening Models SCI-GROW and GENEEC

Due to the lack of extensive monitoring data (with the exception of corn herbicides) and validated basin scale exposure models, OPP’s interim approach for estimating pesticide concentrations in drinking water was to use simpler screening models (SCI-GROW and GENEEC) that had been developed by OPP.

Although OPP performs computer modeling for comparing leaching potentials, it has not previously used modeling to estimate pesticide concentrations in ground water. However, OPP developed SCI-GROW for use in estimating worst-case pesticide concentrations in ground water. SCI-GROW was developed using environmental fate and groundwater monitoring data. The groundwater monitoring data used were obtained from various Prospective Ground Water (PGW) monitoring studies conducted on various chemicals and at various highly vulnerable areas (shallow aquifers coupled with high infiltration soils which have shown detections of the test pesticides). All of the studies from which the data were obtained were required and judged acceptable by OPP.

The regression equations used in SCI-GROW were developed by regressing application-normalized ground water concentrations against the "relative intrinsic leaching potentials" (RILP) of the chemicals. The RILPs depend upon the half-lives and organic-carbon-normalized soil/water partition coefficients of the chemicals. The resulting regression equations can be used to estimate an application-normalized pesticide concentration for a pesticide in highly vulnerable areas from the pesticide's half-life in soil and its organic-carbon-normalized-soil/water-partition coefficient. The estimated application-normalized ground water concentration can then be multiplied by the total application rate in lb/acre to give an estimated ground water concentration for the pesticide in highly vulnerable areas.

Although SCI-GROW is based upon regressions developed from actual ground water monitoring data, it should generally be considered a screening model because the PGW monitoring study data were collected primarily in areas having high rainfall and highly leachable soils over shallow unconfined aquifers. OPP believes that pesticide concentrations in such aquifers are generally substantially higher than in most ground water used for drinking water. The use of SCI-GROW as a ground water screening model for predicting pesticide concentrations was discussed as Topic I of the SAP Meeting agenda.

GENEEC is a more extensive mathematical model designed from output generated by the PRZM and EXAM models. However both SCI-GROW and GENEEC are generic, in that they do not consider differences in climate, soil, topography, or crop in estimating pesticide exposure. GENEEC is used as a tool to specifically estimate a pesticide concentration in a standard water body due to off-target movement of pesticide. This model has been used by OPP primarily in the first-tier risk assessment of pesticide exposure to aquatic life.

OPP uses computer modeling (GENEEC and/or PRZM/EXAMS) to estimate pesticide concentrations in an edge-of-the-field pond for use in screening ecological exposure and risk assessments. Such modeling has also been used as a screen for drinking water assessments. However, edge-of-the-field ponds are not sources of drinking water and estimates of pesticide concentrations in them are likely to be overly conservative for drinking water screens. Consequently, OPP is currently trying to develop more realistic and accurate screens for drinking water. OPP applies a 3-fold "dilution" factor to GENEEC estimates of drinking water.

One of the primary factors contributing to the overly conservative nature of estimated pesticide concentrations in an edge-of-the-field pond is that it is assumed that the pond receives all of the drainage from a 100% cropped field which is 100% treated with pesticide. Watersheds are never 100% cropped and 100% treated. OPP is currently developing conservative pesticide loading reduction factors for application to GENEEC and/or PRZM/EXAMS estimates of pesticide concentrations in edge-of-the-field ponds. The pesticide loading reduction factors are based upon maximum percentages of county or basin areas that are used for crops upon which the pesticide is used. Consequently, they are referred to as Crop Area Factors (CAFs). The assumption is that the percentage of a county cropped is a conservative surrogate for the percentage of a basin cropped and treated with the pesticide. The use of GENEEC and crop based dilution factors for estimating pesticides in runoff and surface water models was discussed in Topic II of the SAP Meeting agenda. (A yet unnamed screening conceptual model intended for use in predicting pesticide concentrations in flowing surface water and drinking water reservoirs was discussed by the Panel in Topic III.)

Available Monitoring Data for Pesticides in Raw and Finished Drinking Water

Background

Although we have useful data from the PGW monitoring studies, the ongoing NAWQA Program and other USGS monitoring studies, the Acetochlor Registration Partnership monitoring study, and ongoing monitoring studies by various states such as Illinois and Ohio, there is no comprehensive, reliable, and appropriate database of pesticide concentrations in drinking water that can be used for all pesticides in conducting dietary risk assessments.

Existing monitoring data are generally unevenly collected regarding use areas and pesticides and degradates; measured levels can vary widely over time and location. Measurements are not always taken from actual drinking water (or water that could realistically be used for drinking), and some data have been collected by targeting areas most likely to be contaminated, while other data have been collected in a more random fashion. Most of the monitoring data that have any utility for exposure assessments are data for a small number of pesticides with a history of intensive use on major agricultural crops. The reality is that what people are exposed to in drinking water is heavily influenced by where they live and the source of their drinking water. Depending on the region of the country (and even the community within a region), exposures to particular pesticides in drinking water could be very high, moderate, low, or non-existent. With the passage of the FQPA, OPP must evaluate and characterize available monitoring data for possible use in human health risk assessment.

Methods for estimating exposure distribution curves for ground water are similar to those for surface water. However, due to the nature of ground water and ground water monitoring studies, there are different concerns and uncertainties that need to be addressed when using ground water monitoring data. These include a strong bias in the data toward very sandy soils in high rainfall areas with high pesticide use, a substantial amount of data being collected from typically more vulnerable wells that are not used for drinking water, the lack of statistical power in many ground water studies due to infrequent detections, and a frequent lack of adequate sampling intervals.

Some studies have focused on drinking water wells. These include the OPP's National Pesticide Survey and the National Alachlor Well Water Survey (NAWWS). Although such studies generally have fewer limitations for drinking water assessments than studies conducted on wells not used for drinking water, they have other limitations. It is often difficult to determine the nature of the wells being used. Because ground water vulnerability tends to be very local in nature, studies with totally random selection of study wells often lack statistical power due to only very few wells having detections.

OPP is currently evaluating the use of Monte Carlo probabilistic assessments for estimating distributions of occupational, dietary, and drinking water exposure. Monte Carlo assessments involve running exposure algorithms numerous times with combinations of the inputs for each run being randomly selected from distributions of the input variables.

Although Monte Carlo assessments are relatively easy to perform using readily available software, the Agency needs to establish guidelines for such assessments to help minimize potentially high uncertainties in the output and the misuse of the output. For example, the upper end of exposure distributions upon which OPP may base its decisions is generally highly sensitive with respect to the selection of input distributions that fit the empirical distributions. Distributions that adequately predict the central portions of the empirical distributions may sometimes grossly underestimate the tails of the distribution.

Correlations between input variables must be taken into account to avoid combinations of input values that would not occur. Methods for including non-detects in the analysis need to be addressed. Biases in the input distributions and their potential impact on the bias of the output distribution should be characterized.

Population-based cumulative frequency distributions of pesticide concentrations in drinking water are a necessary input for Monte Carlo based estimates of pesticide dose distributions due to the consumption of contaminated drinking water. Unfortunately, supplementing or replacing non-existent community water system (CWS) data with monitoring data of natural surface and ground water is difficult because it is difficult to determine what (if any) CWSs or other drinking water supplies the monitored data can be reasonably assumed to represent. OPP envisions the increased use of GIS to determine how representative CWS and natural water monitoring data are of pesticide use areas.

Drinking water exposure depends not only on the concentration of the chemical in drinking water but also on the amount of drinking water being consumed. Drinking water consumption distributions that have been developed and which appear in the literature can be readily used. OPP is currently evaluating whether to use such distributions in Monte Carlo simulations.

Need for Additional Monitoring Data

Because of the limitations of computer modeling and the limitations of available monitoring data, and the requirements of FQPA to conduct cumulative risk assessments, additional data are needed on the concentrations of pesticides and degradates of potential concern in surface water source drinking water. We believe that funding or performing a series of different monitoring studies, each on a single pesticide and its major degradates, would be of limited value in satisfying in a timely manner the cumulative exposure and risk assessment requirements of the FQPA. Consequently, it would be more effective and efficient for a central entity such as the USGS and/or the American Water Works Association (AWWA) to sample water supply systems and analyze the samples for multiple pesticide residues.

OPP believes that it could develop scientifically based criteria for including pesticides and watersheds in a comprehensive monitoring program. The criteria would be based on potential risks associated with the consumption of surface source drinking water and would include considerations of pesticide use distribution, pesticide fate, model estimated concentrations, mammalian toxicology, common modes of action, and watershed soils and hydrology. The use of monitoring data for pesticides in raw and finished drinking water was discussed in Topic IV of the SAP Meeting agenda.

General Panel Comments:

The Agency should be complimented on the work done to develop screening tools while under severe time pressure to make FQPA decisions. The Agency must bear in mind the importance of developing a longer term plan that builds on the screening approaches already considered.

For all of these models, OPP should list all the relevant variables and fully describe their expected impact on conservatism and uncertainty, in order to explain the degree of conservatism inherent in the risk predictions to the public and to risk managers.

OPP is encouraged to invest time and resources into the location, import, and implementation of Geographic Information System (GIS) databases for use in defining subbasins applicable to the assessment problem. The use of these databases, often already available within other agencies, would improve the general assessment process and increase the acceptance of the results among scientists and the public. There have been many applications of GIS in other agencies and databases from USDA, USGS, and Commerce [(e.g., Climate, National Resource Inventory (NRI), AG Census, States Soil Geographic (STATSGO), landuse patterns)]. Use of these databases may increase the potential reliability of the models and, most importantly, speed the development of tools to address the FQPA issues before OPP. The need to validate EXAMS has so far been ignored by the FIFRA Exposure Model Validation Task Force, but this is probably the model most often used for risk assessment purposes. It is recommended that this effort should be rectified as soon as possible by cooperative government, industry, and academic efforts.

The Agency needs to document the detailed process of how an FQPA Drinking Water Exposure Assessment will proceed both through and beyond the screening methods discussed at this SAP, because more definition on higher tier approaches may help clarify the best ways of organizing the screening tiers. It must be made clear that the tools proposed to the SAP are first-tier screening tools and not decision endpoints.

All models should be considered as hypotheses, as it is not known if they can conservatively predict pesticide levels in ground water or surface waters. As such, they should be tested with data and compared to monitoring information to determine their bias in order to learn their limitations and to improve the models accordingly. A first step in this process, however, is to perform a systematic sensitivity test of the model's input parameters to understand those parameters which most impact on the output values from the algorithm. By knowing which inputs are most sensitive, one can then focus effort on obtaining the best data possible for the more sensitive input values. Better judgements about the quality of the predictions can be made based on the data quality for the more sensitive input values. Thus, it is recommended that detailed sensitivity analysis be performed for all models to determine if they are appropriately conservative. While good data are not available for many pesticides, significant and reliable data are available on some of the more heavily used pesticides.

The use of proposed average input parameters, e.g., aerobic $t^{1/2}$, K_{oc}, and use rate, for the SCI-GRO model produces a single output value. However, a single prediction value is not sufficiently informative. A recommended approach is to use Monte Carlo techniques using all data for each parameter to incorporate the full variability of the input data available and to include a display of the uncertainties around the predicted values. A clear distinction between confidence intervals that are associated with the data variability and uncertainty bounds should be made. The incorporation of confidence intervals, because of data variability and uncertainty around the predicted estimates, permits a quantification of the degree of conservatism in the models's prediction. As such, scientific judgement can then be ascribed to the potential for false negatives and false positives for each prediction. A display of confidence intervals and uncertainty bounds is recommended with all the proposed models.

One Panel member believes that SCI-GROW and GENEEC are not appropriate screening models, stating that OPP approaches generally accept that a screening model is a deterministic tool used to generate "high" or "upper-bound" values and to indicate likely "shapes" of the exposures with time. If a product "fails" the screen, it moves to PRZM/EXAMS where the full Monte Carlo/ probabilistic approaches are more appropriate. GENEEC and SCI-GROW have too many "hard-wired" inputs to justify probabilistic analysis (especially given OPP's stated time constraints and need for a Tier 1 "pass/fail.")

All the ideas and models discussed at the meeting should be tested against empirical monitoring data that are available. While it is true that there are not good data for a lot of pesticides, there are significant and reliable data on some of the more heavily used pesticides. Use of these data will not conclusively prove that models are right or wrong, but it will help with "ballpark" estimates of whether they are appropriately conservative.

One Panel member believed that the approach used in all areas was highly conservative, perhaps too conservative. In the context of a first-tier assessment, this approach may be acceptable. However, the second-tier assessment should undergo even more scrutiny to gain more accurate estimates.

OPP should note that, in general, aquatic exposure arising from Surface water sources will be more significant to FQPA risk assessment than those arising from ground water-derived drinking water. Accordingly, if there is any conflict for resource for exposure estimation, the Panel recommends that OPP devote effort primarily toward Surface water, both at a screening level and for Tier 2 and beyond.

TOPIC I: SCI-GROW Ground Screening Model for Predicting Pesticide Concentrations in Water:

General Panel Comments on Topic I:

The consensus of the Panel members was that the use of such models by OPP was an appropriate approach for the first-tier level for drinking water risk assessments. The Panel recommends immediate implementation of SCI-GROW and GENEEC [GENEEC with crop dilution factors as discussed in the set of questions on CAFs and threshold "correction" factors]

There was disagreement as to the degree of conservatism of the model. The majority of the Panel believed that the model was highly conservative, but several members believed otherwise (or at least that the uncertainties should be defined.) One Panel member was concerned that the model is not adequately conservative for the following reasons: First, the model appears to ignore the 40 million + individuals who are receiving their tap water from private wells. Many of these wells fit the definition of highly vulnerable ground water sources -- they are shallow, in sandy soil, and often next to farm fields. Given the existence of these wells, the model is manifestly not conservative. Second, results from the model (which estimates atrazine concentrations at 2-3 ppb) are not conservative based upon actual monitoring results. Numerous studies in non-vulnerable sources have found atrazine at concentrations exceeding 3 ppb. Thus, the model may be underestimating concentrations that are found in both vulnerable and non-vulnerable groundwater sources.

Another Panel member was concerned that the model was designed to estimate maximum concentrations 90 days after a single detection and would significantly underestimate long-term exposures to pesticides. It was this Panel member's opinion that the model is not, at present, appropriate for analysis of human health effects, which need to be based upon how pesticides are actually used. An ideal model must account for many years of pesticide application and also must assume that individuals will be drinking water from the aquifer for many years after pesticides are initially applied and reapplied -- not just for 90 days after an initial application. This Panel member recommended refining the model to make it more conservative. At the very least, consider adding safety factors to results, or presenting results in a range (1-10 ppb) with screening estimates based upon the higher range. This type of range would appear to be consistent with the regression model, which shows variations of at least one log unit.

Concerns were expressed about the extent of deviation of the few PGW study measurements from SCI-GROW predicted values; however, perhaps the key issue should not be the degree of fit with the PGW data used for the regression but the conservatism resulting from the compounding of the assumptions underlying the field studies and hence the conservatism associated with using the regression model results.

Some of the basic assumptions inherent in basing the model on PGW studies include the following:

Class	Factor/Impact
Site characteristics	High infiltration
Site characteristics	Light texture soil
Site characteristics	High rainfall
Site characteristics	Low OM%
Site characteristics	Shallow ground water
Site characteristics	Wells totally surrounded so direction of flow is not relevant
Site characteristics	Wells adjacent to treatment - no offset
Weather/Irrigation	Rainfall supplemented in low months - can lead to unnaturally high annual rainfall/irrigation. The OPP sets different supplementation targets for different studies – frequently 110% of each month's average but sometimes higher.
Weather/Irrigation	Protocol ensures irrigation soon after application if it does not rain
Application timing	Multiple applications may be added as single "slug"
Applications	Maximum rate
Well screens	Maximum length
Sample frequency	Ensures any peak is "seen;" results not averaged across field
Well numbers/timing	Likely to pick up preferential flow due to poor well/lysimeter installation
PGW studies with non detects not included	i.e. The studies on vulnerable products on vulnerable sites which resulted in non-detects were not included.
Aquifer type	Unlikely to be used for drinking water source
Water quality	Raw
Model representativeness	For many compounds, use of leaching in sandy low OM% soils does not represent majority of use region

In regard to the SCI-GROW model, it is important to indicate the number of data points on which the model is based and to provide the errors associated with this model. To determine the degree of conservativeness of the SCI-GROW model, the model should be applied to an independent data set and the percentage of false negatives that occur should be determined to indicate the usefulness of the model as a screening program. Providing estimates of the error associated with determining the amount of pesticide in ground water will be useful in the evaluation of the degree of conservativeness of the model. Most arguments on the model's conservativeness are based on the fact that the curve would tend to be biased upward because of the selection of the cases. However, it is possible that large error bounds could override this conservativeness in some percentage of cases. Furthermore, although restriction to only the more likely problematic situations appears to result in the upward bias noted by OPP, it is also possible that this subset of cases will have a lower estimate of the error term, thus underestimating the degree of variability when applied to a full range of values.

The regression based model is simplistic and may omit many potential variables. However, as a conservative first-tier screening model, it serves the purpose since it is based on worst-case scenarios. However, unless an alternate model is used in the second tier of screening, SCI-GROW may be too conservative (given the gaps in the monitoring data). Because of the small number of data points used to develop the model, and because instances of “no detection” were omitted from model development, some bias toward conservatism may have occurred in model development because the detects were single measurements rather than a series of measurements occurring over a time period.

Panel Responses to Agency Questions on Topic I

1) OPP believes that less than 1% of ground water that is used as drinking water is in shallow aquifers in areas having high rainfall and highly leachable soils. SCI-GROW is based on data collected from these types of aquifers which generally have substantially higher pesticide concentrations than in ground water used for drinking water. Therefore, does the SAP agree that SCI-GROW has the potential to generate conservative estimates of pesticide concentrations in most ground water used for drinking water?

Most SAP Panel members agree that SCI-GROW generates conservative estimates of drinking water for first-tier screens. Reasons for conservatism are summarized below:

a) SCI-GROW is based mainly on OPP prospective ground water studies designed to maximize the opportunity for pesticides to leach into ground water:

-Soil site highly vulnerable to leaching (very sandy, little clay, low organic matter).

-Rainfall supplemented with irrigation to ensure higher than average monthly rainfall for each consecutive month of study. Supplementation of rain with irrigation errs on the side of greater opportunity for encountering rainfall amounts in excess of normal patterns.

-Sites with shallow water tables.

-Sites that represent an unknown but very low percentage of the ground water used as drinking water.

-Sites with wells totally surrounded by treatment area; no dilution with clean water.

-Sites with wells directly adjacent to treatment area; short path to well.

-Maximum rate of pesticide application; multiple treatments may be applied as one massive application.

b) Development of SCI-GROW ignored PGW studies with no ground water detections; only those that produced concentrations were included in the regression data set. Therefore, SCI-GROW reflects a filtered data set that implies greater frequency of observed concentrations than what actually occurred in the PGWs.

As part of the SCI-GROW documentation, the Panel recommends that OPP should list all factors which make the model conservative. One Panel member indicated concern that the sites might represent more than 1% of the ground water used for drinking and that there are monitoring data showing higher concentrations than SCI-GROW's prediction, thus indicating the estimated values are not conservative enough. Further discussion of this topic led to the suggestion that concentration data needed to be placed in perspective with regard to the probability of achieving certain concentration levels. Panel members pointed out that existing ground water monitoring studies indicate that a very small percentage of concentrations are high and that these concentrations are often associated with faulty well construction or point-source contamination. Moreover, surface water concentrations are higher than ground water ones and drive the decisions.

Also, as part of the documentation for SCI-GROW, the Panel recommends that OPP should examine a soils database such as STATSGO and other relevant tools (climate databases, depth-to-groundwater, etc.) to document the occurrence of soils from the typical PGW studies used to develop the regression in SCI-GROW. The Ground Water Loading Effects of Agricultural Management Systems (GLEAMS) bromide leaching data from San Diego supercomputer runs should be utilized to compare the predicted leaching in the SCI-GROW areas relative to the rest of the U.S. This should aid in assigning significance to the conservatism of SCI-GROW.

Another Panel member stressed the importance of expressing concentrations in terms of their likelihood of occurrence. The Panel members emphasized that OPP should attempt to capture SCI-GROW variability, in terms of including the entire range of an input in the SCI-GROW calculation, and to propagate error so that estimates of confidence limits around the SCI-GROW value are captured. Some Panel members believed it was better to use an entire range of input data rather than average values. Finally, a Panel member raised the special case of Karst topography, which is characterized by mass flow of water and pollutant through cracks and fissures directly to ground water. It was suggested that OPP examine existing monitoring data within Karst areas to determine that SCI-GROW remains conservative.

Several Panel members noted that, given that the model results and the field data were uncomfortably close, there is uncertainty over whether the surface area/water volumes used by OPP were appropriate and suggested a need to verify models with actual field data. OPP needs to provide clarification on what the meaning of this first level screen should be. If a pesticide passes the level 1 screen (and is passed on for further screening), does it mean that the pesticide most definitely presents human health risks or does it simply mean that it might and that further review is necessary. In order to be most protective of public health, the level 1 screening should be appropriately conservative, consistent with "filtering out" a reasonable percentage of the safest pesticides.

STATSGO and other relevant tools can be used to determine the true relevance of the PGW site characteristics within the universe of U.S. soils. This analysis could even be extended to be specific for the soils normally associated with each of the major crops. With GIS, the tools are available to develop quantification and to replace "estimates." In the same way, concerns over the relevance of the PGW-type shallow aquifers and the extent to which they are used for drinking water could be addressed by a nationwide survey of the occurrence of drinking water wells, the aquifers from which they draw, the populations they serve, and the way they are constructed.

2) Do SCI-GROW estimates of pesticide concentrations in ground water have the potential of being sufficiently conservative for an initial drinking water screen?

Many Panel members believe that the estimates are appropriately conservative. Some members disagreed. Most members believed that the estimates need to be further tested and verified.

3) The regression equations used in SCI-GROW were developed primarily from data on pesticides with K_{oc} values less than 1000. However, limited ground water monitoring data on pesticides with K_{oc} values greater than 1000 indicate that SCI-GROW estimates for such chemicals are conservative with respect to (greater than) the monitored data. Consequently, should there be any limitations imposed on the use of SCI-GROW, particularly with respect to its extrapolated use on pesticides with K_{oc} values greater than 1000?

There was lack of a consensus regarding the placement of constraints on SCI-GROW for pesticides having K_{oc} values over 1000, because estimates by the model were higher than actual monitoring values. One Panel member noted that observations of estimates higher than data were obtained from “limited ground water monitoring data.” Therefore, a strong basis for recommending constraints does not exist. Is “1000" the proper level to impose the constraints, or would “950" be better? Until more data are obtained, constraints should not be imposed. To help clarify this, the OPP should provide a table showing the predicted values for a product of Koc greater than 1000 relative to monitoring data. The views of several other members are given in the following paragraphs.

The chief limitation for regression models such as SCI-GROW is their inability to extrapolate outside the range of the data set from which they were built. In addition, OPP has already established a leaching cutoff value of $K_{oc} > 500$, beyond which pesticides are deemed not likely to contaminate ground water. For these reasons, it seems reasonable to establish a K_{oc} cutoff value (such as 500) where there is little value from a SCI-GROW drinking water analysis.

Perhaps SCI-GROW should not be conducted for compounds of $K_{oc} > 500$. If it continues to be used for such compounds and they fail SCI-GROW because only a small fraction of the “risk cup” is available for drinking water, then the additional conservatism displayed by SCI-GROW may require some alternative to a request for monitoring studies.

4) What steps beyond the current peer review and characterization of uncertainties should OPP take in using SCI-GROW?

a) The Panel recommends continuation of the comparison of SCI-GROW estimates with those of PRZM. It wonders if the PRZM/VADOFT (Vadose zone Flow and Transport) model could perform as well as SCI-GROW. PRZM is not as generic as SCI-GROW and has the advantage of considering environmental differences, making it more extrapolatable through close ties to weather pattern and soil differences ; SCI-GROW has no such connections and cannot be easily extrapolated to different locations in time and space.

b) The development of SCI-GROW should be fully documented. OPP should include new datasets (including any new ones) and show regression results with confidence limits in the documentation.

c) Continue the comparison of SCI-GROW results to actual monitoring data by performing "case studies."

d) Given that a peer review of SCI-GROW is currently underway in OPP, the Panel recommends extensive documentation and publication of all reviews performed within and outside the Agency.

e) Finally, the Panel recommends expressing SCI-GROW output as a range of values that capture input variability and uncertainty from the regression.

5) Does the SAP have any recommendations for higher tier ground water estimates such as those based on modeling for pesticides with limited or no monitoring data available? Does the SAP recommend the use of models calibrated and/or developed from monitoring data for multiple chemicals across multiple sites?

SCI-GROW can serve as a screen, but it does not work well at higher tiers because of its limited ability to extrapolate to other situations in time and space. It is not probabilistic and lacks connectivity to climate and soil changes. The Panel does not recommend complete dependence upon monitoring to expand coverage of assessment through regression models. The process is very resource-intensive and is not a highly efficient use of resources.

The Panel recommends development of mechanistic leaching models and supporting GIS databases, complemented by field experimentation and monitoring designed to validate and improve models. When opportunities for improving drinking water are evaluated, OPP should consider how many additional leaching studies are needed statistically to expand SCI-GROW coverage to area- or site- specific assessment, keeping in mind that study cost for each ground water study (a single data point) is in the range of $1 to $2 million. This recommendation needs to be balanced against an analysis of costs for the development and validation of mechanistic models that allow more efficient ways of extrapolation to other situations in time and space. The Panel believes that development of necessary GIS databases and mechanistic leaching models connected more closely to climate and soil changes will provide better and more cost-effective drinking water assessment tools than will a regression approach that is dependent wholly upon the conduct of ground water studies. However, mechanistic model development is only worthwhile if there is concurrent development of databases on drinking water wells, etc., to enable model output to be extrapolated to the "real world."

TOPIC II: GENEEC and The Use of Crop Area Factors for Estimating

Pesticide Concentrations in Runoff and Surface Water Models

General Panel Comments on Topic II:

OPP has produced a review of some of the issues associated with incorporating the extent of crop and chemical use in the watershed into drinking water exposure estimates. During the SAP review of this section of the presentation, several key factors were identified. It is important to note that while all of these are important to estimating potential aquatic exposure, only a few are directly related to the CAF issue specifically raised by the Agency.

OPP made a number of assertions in the document and presentations. Comments from the meeting relating to some of these are summarized below:

Assertion	SAP Opinion
"It is, of course, reasonable to assume that a single field receives 100% treatment with a chemical. However, at larger scales, this is unlikely to be the case" RECOMMENDED CHANGE: "In a Tier I conservative assessment, it is reasonable to assume that a single field consists of a single crop which receives 100% treatment with a chemical. At larger scales neither assumption is likely to be correct."	Generally agreed but see suggested change
"While both are important, we will initially be dealing only with the first factor (% cropping) and will assume that 100% of the crop area is treated with the pesticide."	This makes the process an <u>exceptionally</u> conservative assumption.
Cropping data is generally aggregated at its finest level of detail at the county level.	Not correct - NAWQA have used GIRAS LULC data weighted by county dated to produce a finer resolution. It is possible there are other sources of higher resolution data. In addition, NRI has finer levels of detail.
It is reasonable to assume that size of a county roughly approximates the size of a drainage basin capable of supporting a drinking water utility.	Is this supportable with facts? A distribution of basin sizes linked to reservoir sizes linked to population served should be gathered.
For screening level assessments, it is only necessary to identify county or counties with maximum CAF and use this factor.	This is unreasonable because of regional rainfall or agricultural factors. Better to regionalize CAF selection. More importantly counties are not the best calculating unit, the CAFs should be calculated for hydrologic units to match the move to watershed-scale approaches elsewhere in the scientific community.
Physical transport processes are relatively scale independent.	Generally agreed that OPP assumptions were workable while leading to added conservatism.
Position in the basin affects delivery.	Generally agreed that OPP assumptions were workable while leading to added conservatism.

Chemograph varies by position.	Generally agreed that OPP assumptions were workable while leading to added conservatism.
Apply CAF only to chronic estimates.	The SAP generally agreed with this; it is likely that relatively few acute issues will arise.
Site heterogeneity (e.g. soils) tends to lead to overestimation of exposure.	True but not truly a CAF factor -- applies equally to the presence of variable slopes, tillage, ditches, mitigation measures, etc.

In general, the Panel members were supportive of OPP's initiative to introduce CAFs into exposure assessment. However, the Panel posed several questions or comments to which OPP scientists responded:

OPP scientists confirmed that they were still considering the issue of whether the 3-fold "real-world" factor for adjusting GENEEC-predicted exposures should be used in addition to the CAF.

In questioning OPP's method of taking the maximum value of the CAF from across the Nation and applying it to the scenario selected for modeling, irrespective of the region, OPP scientists explained that, because they tend to select crop-relevant scenarios for the exposure modeling, it is unlikely that major discrepancies would result. In response to the Panel's related comment that the use of GIS Approaches would permit the development of a regionally based CAF database, OPP scientists agreed that a regional approach would be feasible while more sophisticated cropping databases are developed.

OPP scientists agreed with a Panel comment that OPP should move toward incorporating pesticide usage data based on hydrologic units rather than political boundaries (counties can contain multiple watersheds and counties in the West can be very large), but the use of county-based CAFs will provide a workable interim solution.

To a Panel question on the usefulness of incorporating sales or usage data, OPP responded that, although these data are desirable, some of the data are available only at a state level and that high-resolution data would be required.

OPP scientists agreed with a Panel comment that it would be valuable to "validate" the CAF approach – a particular example suggested was the extensive data available for corn herbicides in the Midwest.

Panel Responses to Agency Questions on Topic II:

1) The ecological risk scenario provided in OPP's presentation of GENEEC is based upon a 10 hectare field draining into a 20 million liter pond. Will this ratio be conservative enough to protect a small basin which is capable of supporting a drinking water facility?

In response to this question nearly all the Panel members agreed that the pesticide concentration estimates provided by GENEEC are most likely overly conservative. They are conservative for the following combination of reasons:

a) Pond is assumed to be at the edge of a treated field with no intervening buffer of any sort and is completely surrounded by the field. The entire basin is planted to crops and treated with pesticides.

b) GENEEC uses a high runoff scenario; a constant 10% fraction of the material in the top inch of soil is assumed to run off, regardless of pesticide properties.

c) The 90^{th} percentile spray drift fraction is assumed, based on 10mph winds.

d) Chemical inputs are adjusted for maximum runoff (lowest Koc and highest laboratory soil half life).

e) Water photolysis is minimized per EXAMS; soil photolysis, when relevant, is not included.

f) No dilution of the pond occurs from the runoff event.

g) It is assumed that application of pesticide occurs on the same day over the entire basin.

h) It is assumed a basin receives the same high level of rain on the same day across its entirety to cause runoff into the drinking water supply.

i) This event occurs without adjustment of drinking water concentration by dilution from untreated areas or by diversion of contaminated flow into local ponds not connected to a drinking water supply.

OPP should attempt to characterize actual basin/drinking water source ratios to get a better idea of how the ratio cited above fits into the range of ratios. As a place to begin, OPP can utilize information from the existing OPP pond database, which provides watershed/pond ratios for a variety of locations across the country, or it can use data from AWWA to characterize water volume of static water bodies used by CWSs, the flow rate and cross section of flowing waters, etc., and the associated catchment areas. These data could be used to generate distribution curves to position the ecological risk assessment pond scenario into a useful drinking water context. Panel members also thought that perhaps monitoring data from worst-case basin/water supply sites could be found and used to provide an idea of more realistic values.

A final recommendation is to make sure that GENEEC gets updated whenever PRZM3/EXAMS model refinements are made in order to keep GENEEC current.

2) Is the use of Crop Area Factors to adjust modeled concentrations of pesticides in field ponds a reasonable approach to providing more accurate yet appropriately conservative estimates in surface water for screening drinking water exposure assessments?

Yes, but, because the ultimate goal should be to develop as accurate an exposure estimate as possible (consistent with protecting the resource), OPP should use the percentage of the crop treated as few products ever reach greater than half the total market and very rarely become ubiquitous even in very small watersheds. Even if this factor is included, the many conservative factors compounded in the assessment [e.g., rainfall timing/runoff assumed to be simultaneous across watershed, simultaneous application of pesticide to all acres, etc. (see above)], will ensure that the exposure estimate will remain highly conservative.

The use of crop area factors with GENEEC or PRZM/EXAMS greatly improves the accuracy of the models and results in conservative estimates. GENEEC seems to be overly conservative given that it doesn't take into account regions, crops, soils, etc. A weakness with GENEEC is that it relies on pesticide degradation and sorption to soil and ignores the fact that most pesticides are applied to crop material, living or dead, (as with residues in a no-tillage area). This means that before the crop ever contacts the soil, it could be subject to uptake and metabolism by the plant, sorption to the plant, volatilization, or photo-decomposition. The two-day delay before rainfall assumed by the model is sufficient time for loss of pesticide by any of the mechanisms listed.

It was questioned if the 10 hectare field draining into the 20 million liter pond is the appropriate surface area volume. (See also comments on Question 1.) OPP staff indicated that they were concerned that results were not conservative enough, perhaps because the surface area/volume ratio is not appropriate. Given these concerns, OPP should not finalize the model until this issue can be clarified. OPP should use existing data from the USGS, or from AWWA to determine the range of surface area /volume ratio's for a number of existing water systems using reservoirs.

3) Is summing the areas of different crops in a county where a particular pesticide is used an appropriate use of the CAF for acute assessments? For chronic assessments?

In principle, if the compound is to be used at the same time on more than one minor crop, additivity may be applicable, but using this simple approach will tend to generate even more conservative assumptions since it appears highly unlikely that the same county will be the maximum producer of more than one crop. If the timing of application or the application methods differ substantially, then more care should be taken. However, before combining CAFs, the Agency should ascertain that the product label permits its use on all crops in that region.

The SAP supports and recommends the generation of a database capable of providing total potential use of a product on a regional basis. From this database, only regionally relevant CAFs should be selected.

Most importantly, the SAP recommends that the computing unit for CAFs be adjusted from the county to a physio-graphically relevant unit (e.g., hydrologic units (HUs) at the HUC 6 or HUC8 scales) along the lines adopted by NAWQA. The SAP believes that a great deal of the work of determining crop composition on a watershed scale has already been completed by USGS to aid the selection of the NAWQA study units, and the SAP recommends that OPP consult with relevant USGS scientists.

The Panel had no strong views on the use of CAFs for acute risk assessments but believed it was unlikely to be a frequent issue. It is certainly an appropriate and highly conservative approach to use CAFs for chronic assessments.

4) Are there any other sources of data that should be considered in developing this method that OPP has overlooked?

The Panel listed the following existing data as potentially of value to effectively using the CAF approach:

Data from Dr. Len Gianessi, National Center For Agricultural Statistics, Washington, DC.

Data collected by California OPP on pesticide use. California has strong use reporting laws and has use data available in a format that can be applied at the watershed level.

The AWWA is a source of watershed information relevant to CWSs -- particularly watershed area to volume data.

NRI Dataset - this dataset, although difficult to access, is becoming more approachable through the development of tools in USGS and USDA-ARS. It has been used to achieve resolution below the county scale since it uses a combination of HUC8, Major Land Resource Area (MLRA) and county information to locate each sampling unit.

USGS HUC datasets.

USGS DLGs.

USEPA Reach file (RF3).

USDA and "Gianessi and Puffer" (RFF) databases on pesticide usage (county level data may also be available to OPP through Doanes.)

USGS Geographic Information Retrieval and Analysis System (GIRAS) Land Use Land Cover data.

NAWQA databases.

Historic records of watersheds that have generated "problems."

EPA Office of Research and Development nationwide database of ponds relating pond area/depth to catchment area on a regional basis.

5**) Are there other assumptions or limitations to using CAF's that OPP has not considered?**

Yes, a non-exhaustive list of the key assumptions and limitations is provided below. In addition, the SAP commented that, as with all of the issues raised before this panel, the OPP should carefully and thoroughly document all factors and indicate how they are expected to contribute to uncertainty and conservatism in the risk assessment and try to rank their significance:

-Size of basin relative to the Land Use/Land Cover (LULC) and pesticide/fertilizer use data available
-Percentage of each crop in the basin (NOT in the county).
-Probability of use of Compound X on one or more of these crops.
-Likelihood of use of product at the same time:
-on the same crop across the basin (on the same day).
-on different crops.
-Catchment area of basin relative to volume of reservoir/river base flow level.
-Extent of flow-through through the reservoir/river supplying the CWS
-Proximity of crops to water bodies within the basin.
-Probability of a "homogenous rainfall/wind speed-direction" across the basin causing intense runoff at the same time across the whole basin.
-Current runoff models (GENEEC and PRZM/EXAMS) generate values reflective of the edge of the field and not generally appropriate to drinking water.
-GENEEC is based on a runoff-prone SE site.
-Pond assumptions do not substantially allow for flow-through or dilution as a result of runoff.-
-The fact that these estimates refer to "raw" surface water rather than treated drinking water.

Particularly important is a review to understand how given CWSs fit into the overall distribution of water supplies in terms of their reliance on ground water and/or surface water (or the extent to which they combine them) and on the ratio of watershed area to reservoir/river volume.

6) Is the use of CAFs less conservative on long term surface water concentrations than might be expected? If so, how can this approach be modified to be more conservative?

The SAP believes that the CAF approach is reasonable and, when used with GENEEC, it will still provide very conservative estimates of drinking water exposure. However, the large amounts of data available for the Midwest should be examined to see the extent to which this validates the combined exposure assessment approach including CAFs. The Panel members support the inclusion of the pesticide usage data into the assessment.

7) What additional steps beyond this peer review and characterization should OPP take before implementing the use of CAFs?

The Panel suggested that OPP develop/acquire a rich GIS database to enable sophisticated assessments of land and pesticide use within watersheds (as opposed to counties). This would enable the development of aquatic surface water exposure assessment tools both for screening and more sophisticated purposes. Suggested areas for detailed action are listed in the answers above. Until that database is available, the SAP recommends OPP implement the CAF and related pesticide usage factors as soon as possible. The Panel recommended verifying the model with existing data and obtaining more information on appropriate basin and reservoir sizes to use in the model.

Topic III: Conceptual Screening Model for Predicting Pesticide Concentrations in Flowing Surface Water and Drinking Water Reservoirs

Panel Responses to Agency Questions on Topic III

1) Could the proposed conceptual model potentially result in more accurate (but still conservative) estimates of pesticide concentrations in surface water used for drinking water than estimates using GENEEC or PRZM/EXAMS for an edge-of-the-field pond?

The proposed screening model is a conceptual model and has the potential to provide a more comprehensive assessment at the landscape and river-reservoir scale than other models. Given the current status of the model, there is ample opportunity to refine the concept before testing and application. The approach will provide a conservative estimate because the model assumes opportunities for maximum runoff from the surrounding land into the river, steady state conditions in terms of water flow, application rates that cover the land area immediately adjacent to the river, and constant runoff rates from the entire land area. One of the concerns expressed was that the model did not consider any variations in ground cover or crop residue that would have a major impact on pesticide runoff into streams and rivers.

There is a need to evaluate the model in a more regional context because of the linkages between climate, runoff, pesticide application, and hydrology. These refinements would better relate the model to a basin scale setting rather than a county boundary setting.

This model should more closely approximate drinking water than GENEEC alone. Recommendations are to work through trial examples and to compare results to those of GENEEC/CAFs and to actual monitoring data.

2) Could a model based upon the conceptual model potentially result in estimates of pesticide concentrations in surface water used for drinking water that are sufficiently conservative for an initial drinking water screen?

The model would produce conservative estimates. There is a need to document all of the assumptions within the model to be able to track the conservative evaluations that are made and how they potentially interact with one another.

Selection of model input values will have a big impact on outcome and must be done carefully. The flow rate and reservoir volume terms seem to be the critical variables that might allow the model to predict any desired value. It might be better to take some real watersheds of known dimensions/scale and design a model to fit the known reservoir sizes, watershed areas and flow rates. A matching effort using GIS could then be used to put the selected watershed(s) into context in terms of flowing water systems at risk.

3) What limitations should be imposed on the use of the proposed conceptual screening surface water model?

The model as proposed should be used only as a screening tool because of the limitations incorporated into the development, e.g., steady state conditions, uniform runoff from the surrounding land area. The model is an initial attempt at the landscape and basin scale approach and has utility for this level. However, the model is not probabilistic, it does not capture the probability of achieving specific concentrations in drinking water, and is not coupled with soil or climate differences. It is designed to be conservative and thus must serve only as a first screen of drinking water concentrations.

Furthermore, the model is not designed to provide final estimates. The Panel recommends that OPP continue to support the development of more sophisticated watershed-based modeling capability to provide exposure analysis tools based on a "basin" until beyond the initial screen. OPP should implement GIS capabilities and obtain supporting databases in order to be able to provide specific site assessments with regard to drinking water assessments for CWSs and should consider basing estimates on hydrologic cataloging units (HUCs) rather than on political boundaries.

The model will need to be tested/validated against real data sets before being used. The implications of scale associated with using the 5-ha study units on either side of the 100-meter wide-river need to be considered in terms of the percentage of a true watershed that is being considered. As designed, this greatly magnifies spray drift risk to very conservative levels.

4) Does the SAP have any recommendations for improving the proposed conceptual screening model or for generating conservative model input?

The model should be considered as an initial attempt and efforts should be made to support the development of a more comprehensive model that could be used in the second-tier approaches. The estimates generated by the model would be conservative based on the current assumptions within the conceptual model. This model, however, could be evaluated with stream discharge and sediment data to determine if the hydrological components are representative, and the pesticide component could be evaluated, thus reducing problems in identifying appropriate data sets with pesticide data.

The Panel recommends multiple runs with different combinations of input to determine the model's response with respect to output. Comparison to actual monitoring data through case studies will help to adjust input into appropriate conservative range. The details for input and boundary values that drive the model are critical determinants of the level of conservatism produced by the model.

As with other areas, the Agency should list all the relevant variables and categorize their likely impact on conservative prediction of exposure. For example:

- The likelihood of runoff being the same throughout the watershed
- No mitigation due to riparian areas
- No reduction of spray drift entry due to riparian vegetation
- 100% treated
- Only 5-Ha corridor along river is assessed
- Many runoff events with first occurring 1 day after each application
- No change in base flow
- Even slope
- Storm covers entire watershed at the same time
- Wind speed gives high drift
- All of the watershed treated on the same day

The Agency should consider whether it is more effective to use a meta-model of a Tier 2 model as the screening tier since this is easier to update as the Tier 2 model is refined.

Regarding recommendations for improving the proposed conceptual screening model, the Panel questions if the use of crop area factors in this model adequately consider the fact that most pesticides are applied to a crop canopy or crop residues rather than bare soil.

5) Does the SAP recommend any alternative screening level approaches for providing more accurate yet sufficiently conservative estimates of pesticide concentrations in surface water used as drinking water? In particular, does the SAP believe that a more empirical regression based approach similar to SCI-GROW for ground water is also feasible for surface water provided that any regression equation developed from data on a particular
basin is only applied to the same basin?

There were two schools of thought on the use of regression models or more empirical methods.   Some Panel members believed there was value in developing regression approaches similar to SCI-GROW, while others thought that attention should be directed toward a more regional basin-scale model.   The value of the regression approach would be to obtain an evaluation of the range of dilution factors that may be encountered within a basin.   The empirical methods may provide a quick method of obtaining some assessment of the basin scale and reservoir values that would not be readily available mechanistic models that are more data intensive.

The Panel recommends that OPP continue development of the existing model as a first screen. Further assessment of drinking water concentrations beyond the initial screen should be conducted via watershed-scale modeling capabilities coupled to GIS and use of supporting databases.

The SCI-GROW approach for surface water as alternative methodology will be highly resource-intensive and a very inefficient use of resources. Many basins exist, and to develop regression models for each would be a daunting task. The Panel believes a more effective approach would be to develop watershed-scaling modeling tools linked probabilistically to weather patterns and GIS. Development of GIS capability plus getting the proper supporting databases online requires effort initially, but once these systems are online, additional effort required to use them are minimal and their value outweighs the effort.

Use of compounds of several differing levels of Koc and half life (e.g. atrazine and chlorpyrifos) might improve the general applicability of such a tool. Note that this alternative approach is subtly different from both the screening model and the "regression" approach used in SCI-GROW. This approach would be easy and quick to implement and could serve as a Tier 1 screen to replace GENEEC (pond based) and be usable well before the new OPP surface water screening model..

A Panel member proposed that OPP consider using a regional reference compound approach, coupled with relative toxicity, relative use, and relative runoff potential (as provided by the GENEEC model) as a Tier 1 screening tool to assess the contributions of drinking water to the total dietary risk. Rationale for, and elements for, the method include the following:

[Note: the "cupful" terminology used below is a very convenient and useful tool to describe the maximum allowable safe dose of a particular pesticide for a particular endpoint (acute, chronic non-cancer, and chronic cancer) from aggregate exposure through all pathways (food, water, air, skin adsorption). These doses are generally determined through the application of safety factors to data generated from animal toxicity studies. The immediate task of OPP is to screen pesticides in relation to the importance of drinking water pathways to the "cupful."]

a) A regional reference compound would be one for which ample monitoring data are available in the area of interest. Atrazine in midwestern water supplies will be used as an example, with the population exceedency curves for atrazine generated in the acetochlor monitoring study taken as a first-order estimate of the distribution of atrazine concentrations in vulnerable surface water supplies in the Midwest. (See the population exceedency curves from the presentation and discussions in the Use of Monitoring Data summary.)

b) The contributions of drinking water for the reference compound to the total dietary load (cupful at the appropriate standard) for acute, chronic non-cancer, and chronic cancer endpoints can be assessed through analyses of the population exceedency curves, with Y axes showing the ratio of the atrazine concentrations to the "cupful." (See SAP discussion in TOPIC IV on use of monitoring data.)

c) The population exceedency curve for the reference compound represents the interrelationships among all of the factors that affect pesticide concentrations in the region, including pesticide use, the physical, chemical, and biological properties of the pesticide, the soils and hydrology of the region, and the vulnerability of the CWSs in the region.

d) For compounds in the same region but lacking monitoring data (pesticide Y), estimates of the role of their drinking water concentrations toward filling their "cupfuls" can be made in the relation to the reference compound (atrazine) using the relationships shown in Figure 1. [The relative toxicity multiplied by the relative runoff potential (per unit application, as predicted by GENEEC) provides an estimate of the contribution of drinking water exposures for pesticide Y to the "cupful" for pesticide Y, relative to the contribution of drinking water concentrations of atrazine to the corresponding atrazine cupful.]

e) Application of this approach for assessing the role of drinking water pathways for an acute dietary risk is shown in Figure 2, using butylate as an example. For relative toxicity, the one-day health advisories for a child for butylate and atrazine are used. Since the drinking water standards are inverse to toxicity, the one-day health advisory of atrazine is divided by the one-day health advisory for butylate. Use data for atrazine and butylate were obtained for the Great Lakes region. Since GENEEC runs for atrazine and butylate, with unit application rates (1 lb per acre) were not available, this factor in the relative assessment for butylate will be assumed to be one. For acute assessments, the maximum concentrations from the GENEEC runs should be used. From the above approach, the contribution of butylate to its acute "cupful" is predicted to be 0.0025 (0.25%) of the contribution of atrazine to its acute "cupful."

f) Application of this approach to a chronic non-cancer assessment is shown in Figure 3, using terbufos as an example. For relative toxicity, use the reference doses (RfDs) or the drinking water equivalent levels (DWELs) for atrazine and terbufos. Use data for atrazine and terbufos were obtained from data for the Great Lakes Region. For GENEEC, use the 56 day concentrations. In the absence of GENEEC runs, use 1 for the relative tendency of atrazine and terbufos to move from fields to ponds. The results of the relative comparison for terbufos, lacking the GENEEC runs, suggests that drinking water pathways for terbufos could contribute twice as much to total dietary cupful for chronic non-cancer effects as atrazine does to its chronic non-cancer cupful. The relative toxicity multiplied by the relative exposure provides an estimate of the contribution of drinking water exposures for pesticide Y to the "cupful" for pesticide Y, relative to the contribution of drinking water concentration of atrazine to the corresponding

FQPA Dietary Risk Assessment: Drinking Water Component

Combined Monitoring, Modeling and
Relative Risk Approach for Tier 1 Assessments

4. Use of atrazine as a benchmark for relative risk estimates for other pesticides.

Relative Toxicity x Relative Exposure = Relative Risk (RR)

$$\frac{\text{Toxicity}_{\text{pest Y}}}{\text{Toxicity}_{\text{atrazine}}} \times \frac{\text{Use}_{\text{pest Y}}}{\text{Use}_{\text{atrazine*}}} \times \frac{\text{RGENEEC}_{\text{pest Y}}}{\text{RGENEEC}_{\text{atrazine**}}} = \text{RR}_{\text{pest Y/atrazine}}$$

*Use based on regional information for area of interest.

**RGENEEC incorporates effects of soil/water partition coefficients and soil and water half lives.
R in RGENEEC indicates runs using standard application rate of 1 lb/acre.

Figure 1

FQPA Dietary Risk Assessment:
Drinking Water Component

Combined Monitoring, Modeling and
Relative Risk Approach for Tier 1 Assessments

5. Application of approach to acute dietary risks

A. For toxicity values, use one-day HA for children from EPA's Drinking Water Regulations and Health Advisories

B. For use, see data for region of interest.

C. For RGENEEC, use maximum concentration.

EQUATION

$$\frac{\text{1-day HA}_{\text{atrazine}}}{\text{1-day HA}_{\text{pest Y}}} \times \frac{\text{Use}_{\text{pest Y}}}{\text{Use}_{\text{atrazine}}} \times \frac{\text{RGENEEC}_{\text{pest Y}}}{\text{RGENEEC}_{\text{atrazine}}} = \text{RR}_{\text{pest Y/atrazine}}$$

Example: Butylate in the Great Lakes Region

$$\frac{100\ \mu g/L}{2000\ \mu g/L} \times \frac{177\ \text{tons}}{3{,}320\ \text{tons}} \times \frac{\text{RGENEEC}_{\text{pest Y}}}{\text{RGENEEC}_{\text{atrazine}}} = \text{RR}_{\text{pest Y/atrazine}}$$

$$0.05 \quad x \quad 0.05 \quad x \quad 1(?) \quad = \quad 0.0025\ \text{RR}_{\text{butylate/atrazine}}$$

Use data from GAO Report (GAO/RCED-93-128), Issues Concerning Pesticides Used in the Great Lakes Watershed. 1993

Figure 2

atrazine "cupful." The relative exposure is estimated by multiplying the relative use by the relative runoff potential per unit application, as determined by GENEEC.

g) Application of this approach to chronic cancer assessment is shown in Figure 4, using chlorothalonil as an example. For relative toxicity, use the concentrations yielding a 1 x 10^{-4} risk level , as listed in the drinking water standards -- although FQPA requires a higher standard.

Use data for atrazine and chlorothalonil were obtained from data for the Great Lakes. For GENEEC, use the 56 day values. Since these are not available, a value of one has been used in the example. From the above, the drinking water pathway for chlorothalonil appears to contribute about 0.0053 (0.53%) toward its cancer "cupful" as atrazine does toward its cancer "cupful."

TOPIC IV: The Use of Monitoring Data for Drinking Water Exposure and Risk Assessments

General Panel comments on Topic IV:

It is important to note that, as separate data sets, monitoring and modeling have several deficiencies. However, in combination, the monitoring will represent a "real-world" combination of variables that can be used to validate/ calibrate model predictions that serve to extrapolate relative sparse (at best) monitoring data into a probabilistic framework for both spatial and temporal dimensions.

FQPA Dietary Risk Assessment:
Drinking Water Component

Combined Monitoring, Modeling and Relative Risk Approach for Tier 1 Assessments

6. Application of approach to chronic non-cancer risks

   A. For toxicity values, use Reference Dose (RfD) or Drinking Water Equivalent Level (DWEL) EPA's Drinking Water Regulations and Health Advisories

   B. For use, see data for region of interest.

   C. For RGENEEC, use 90 day TWMC or 90 day average

Equation

$$\frac{\text{DWEL}_{\text{atrazine}}}{\text{DWEL}_{\text{pest Y}}} \times \frac{\text{Use}_{\text{pest Y}}}{\text{Use}_{\text{atrazine}}} \times \frac{\text{RGENEEC}_{\text{pest Y}}}{\text{RGENEEC}_{\text{atrazine}}} = \text{RR}_{\text{pest Y/atrazine}}$$

Example: Terbufos in the Great Lakes Region

$$\frac{200\ \mu g/L}{5\ \mu g/L} \times \frac{208\ \text{tons}}{3{,}320\ \text{tons}} \times \frac{\text{RGENEEC}_{\text{pest Y}}}{\text{RGENEEC}_{\text{atrazine}}} = \text{RR}_{\text{pest Y/atrazine}}$$

$$40 \times 0.05 \times <1(?) = <2\ \text{RR}\ (?)\ \text{terbufos/atrazine}$$

Use data from GAO Report (GAO/RCED-93-128), Issues Concerning Pesticides Used in the Great Lakes Watershed. 1993.

Figure 3

FQPA Dietary Risk Assessment:
Drinking Water Component

Combined Monitoring, Modeling and
Relative Risk Approach for Tier 1 Assessments

7. Application of approach to chronic cancer risks

   A. For toxicity values, use mg/L at 10^{-4} Cancer Risk from EPA's Drinking Water Regulations and Health Advisories or other sources of cancer potency factors.

   B. For use, see data for region of interest.

   C. For RGENEEC, USE 90 day TWMC or 90 day average

Equation

$$\frac{10^{-4}\ \text{risk}_{\text{atrazine}}}{10^{-4}\ \text{risk}_{\text{pest Y}}} \times \frac{\text{Use}_{\text{pest Y}}}{\text{Use}_{\text{atrazine}}} \times \frac{\text{RGENEEC}_{\text{pest Y}}}{\text{RGENEEC}_{\text{atrazine}}} = \text{RR}_{\text{pest Y/atrazine}}$$

Example: Chlorothalonil in the Great Lakes Region

$$\frac{0.016\ \text{mg/L}}{0.15\ \text{mg/L}} \times \frac{159\ \text{tons}}{3{,}320\ \text{tons}} \times \frac{\text{RGENEEC}_{\text{chlorothalonil}}}{\text{RGENEEC}_{\text{atrazine}}} = \text{RR}_{\text{pest Y/atrazine}}$$

$$0.11 \times 0.048 \times 1(?) = 0.0053\ (?)\ \text{RR}_{\text{chlorothalonil/atrazine}}$$

Use data from GAO Report (GAO/RCED-93-128), Issues Concerning Pesticides Used in the Great Lakes Watershed. 1993.

Chlorothalonil is a fungicide used on vegetable crops and fruit trees

Figure 4

When substantial monitoring data are not available for a pesticide, OPP can still use the existing data to get a "yes" answer indicating a need for a more detailed evaluation. For example, if a pesticide has been found at levels of concern in a significant number of drinking water systems or sources, it should continue in the process and receive further screening. A lack of monitoring data does not necessarily mean that the pesticide should not be further evaluated, but positive data at levels of concern definitely mean that it should receive further evaluation.

The main limitation of using existing Safe Water Drinking Act (SDWA) or other CWS screening data sets is that they are often incomplete or that sampling only occurs infrequently. In these cases,, OPP should make cautious use of the data.

One Panel member suggested making use of BASINS data set and tools as well as other non-point-source databases.

Panel Responses to Agency Questions on Topic IV

1) Ground and surface water monitoring data have been unevenly collected by different groups using different sampling strategies, methods, and limits of detection. Most of the available monitoring data appropriate for drinking water exposure assessments are for a small number of pesticides with a history of intensive use on major agricultural crops. Does the SAP have any general suggestions on how to best use existing monitoring data for estimating pesticide concentrations in drinking water under the following conditions:

(a) Substantial data exist for most to all use areas
(b) More moderate amounts of data exist for some use areas
(c) Only limited data are available

When available monitoring data are used, whether it's substantial, moderate, or limited, the exposure assessments should attempt to display the uncertainties associated with the precision and bias of the exposure distributions. Monte Carlo approaches should be employed to permit the incorporation of the full variability and quality of the monitoring data. This approach permits a more qualitative description of the limitations, if any, of the data used in the assessment.

The large percentage of nondetectable measurements (e.g., up to 50%) as a result of the limits of detection in the various databases employed is not viewed as a serious problem, if the objective is to estimate the upper end of the distribution (e.g., >90^{th} percentile). However, accurately describing the mean does become highly problematic.

If at all practical, it is recommended that a mega-monitoring database for surface and ground water be constructed, combining all data available from all sources. The degree of data quality should be defined in broad terms to guide when to use all or only the best data for evaluating impact on assessments. Also, the sampling frequency used to produce the observations in the database should be considered in assessments for pesticides with acute endpoints of toxicity. (See answer to Question 2, below.)

When substantial data are available for drinking water supplies, or for source water for a known set of water supplies, the data can be directly used to characterize exposures. OPP's presentation of population exceedency data for maximum observed atrazine concentrations for those water supplies included in the acetochlor surface water monitoring program represents appropriate use of monitoring data for drinking water exposure assessment.

When substantial data exist, the distribution of the data reflects the interactions, within the source water areas, of various factors that influence the concentrations of pesticides in drinking water supplies. For each source, these include a) pesticide use and application, b) the soils, c) the natural and man-made physical features that affect the hydrological responses within the source area, d) the weather conditions and rainfall timing relative to pesticide usage during the monitoring period, e) the vulnerability of the water supply, and f) any treatment provided by the water supply. Consequently, data sets, such as those presented in the atrazine population exceedency graph, present a set of real world "consequences" of the interactions of the factors listed above. Since models attempt, at varying levels of detail, to predict the consequences of the above interactions, the monitoring data support evaluation of the effectiveness of the models in prediction of pesticide concentrations in drinking water and are best used in tandem with modeling estimates.

Where less data are available, as in questions 1b and 1c, the data can be used to directly assess drinking water exposures for the water supplies to which the data are relevant. If models are found to be reliable in predicting pesticide concentrations in data-rich settings, the models can then be applied to the data-poor areas, using whatever data are available to evaluate the applicability of the model in those settings. In data-poor situations, the available data can be used in a screening sense. If they exceed or approach water quality standards, the pesticide in question should receive further study (Tier 2).

Evaluate the use of a "benchmarking" approach with retrospective examination of crop and chemical use to try to determine the correlation between measured residues in rivers, reservoirs, and drinking water, and correlate the distribution of those values with GENEEC "pond scenario" estimates to provide a distribution of dilution factors.

Use "benchmarking" if "moderate" does not mean the dataset is too small to be of value.

In all cases, a watershed unit should be used (as opposed to a county) and modeling should accompany monitoring . (Use hydrologic units at a suitable scale, e.g, HUC 6, 8, 11.) Consider using non-pesticide water quality parameters as surrogates for certain issues, e.g., nitrates / total suspended solids.

Use of these data will help validate the models and link to a GIS usage database that the SAP recommends.

2) Do the time weighted mean and cumulative frequency curve approaches presented for using monitoring data in drinking water exposure and risk assessments appear to

be reasonable approaches for describing the variability and characteristics of monitoring data?

For chronic or cancer endpoints of toxicity, the use of time-weighted mean and cumulative frequency curves appears to be appropriate. However, the interval of time measurements becomes much more important for acute exposures, where peak episodes need to be preserved for the assessments. In both cases, the uncertainty of the distributions should be displayed.

Calculation of time-weighted means is essential where any kind of stratified sampling has been used to characterize pesticide concentrations. Since sampling frequencies are often higher during the runoff season following pesticide application than during other times of the year, and are often higher during storm events than during non-event periods, use of time weighting is essential. In using population exceedency curves, OPP should stipulate the characteristics of the community water supplies (or private supplies) included in the graph. Such curves may be limited to vulnerable supplies within the pesticide use region (as the atrazine data from the acetochlor study that was presented), to all of the supplies in a state, to a multistate area, or to the U.S. as a whole. Interpretation of the exceedency distribution should always be done in the context of the particular supplies included in the study.

Since the context of this Panel is to assess the contribution of drinking water supplies to the total dietary exposure (aggregate risk), adding a separate Y-axis to the cumulative population curves and showing the proportion of the total dietary maximum acceptable dose (the safe cupful) associated with various concentrations of pesticide in drinking water would be useful. (Examples of additional Y-axes are shown in figures 5 and 6, as they apply to the atrazine data from the acetochlor study.)

For acute risks, a population exceedency curve for annual peak values is appropriate (figure 5). While one Y axis would present the atrazine concentration, the second Y axis could contain the ratio of the atrazine concentration to the 1-day, child health advisory for atrazine. For atrazine, this value is 100 µg/L. From such an axis, one could state that the maximum observed peak value represented 0.18 or 18% of the allowable total dietary load. Also, for 90% of the population, the daily drinking water concentrations represented less than 0.045 or 4.5% of the safe total load.

For chronic non-cancer risks from atrazine, a population exceedency curve for time-weighted mean concentrations (TWMC) is appropriate (figure 6). An additional Y axis could represent the ratio of the atrazine TWMC to the Drinking Water Equivalent Level (DWEL) of the reference dose (RfD). For 90% of the drinking water supplies, the TWMC represents less than 0.005 (0.5%) of the DWEL. For evaluation of chronic cancer risks from individual supplies, the Y axis could be the ratio of the atrazine TWMC to the atrazine concentration thought to represent an additional lifetime cancer risk of 1×10^{-4}.

For estimating overall cancer risks associated with the occurrence of atrazine in drinking water, it is also useful to calculate a Population Weighted Mean Concentration (PWMC) for the

FQPA Dietary Risk Assessment: Drinking Water Component

Combined Monitoring, Modeling and
Relative Risk Approach for Tier 1 Assessments

3.A. Acute risks from atrazine in drinking water

-One-day health advisories for children provide a possible basis for evaluation of acute risks

-For atrazine the one day health advisory for a child is 100 ug/L

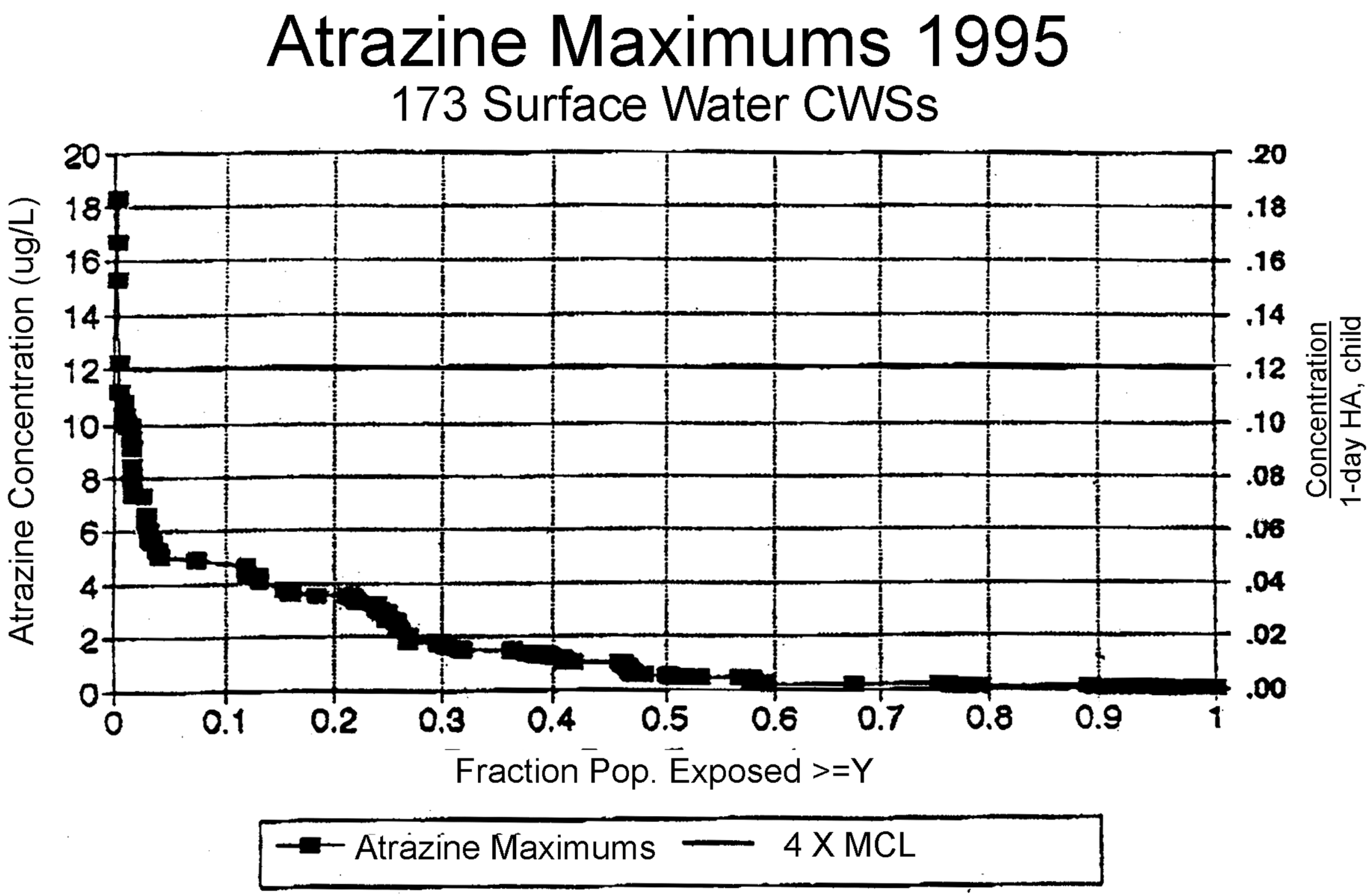


Figure 5

FQPA Dietary Risk Assessment: Drinking Water Component

Combined Monitoring, Modeling and
Relative Risk Approach for Tier 1 Assessments

3.B. Chronic non-cancer risks from atrazine in drinking water

The drinking water equivalent level (DWEL) of the referenced dose (RfD) is an appropriate basis for evaluating chronic non-cancer risks.

For atrazine the DWEL is 200 ug/L

Atrazine TWMCs 1995

173 Surface Water CWSs

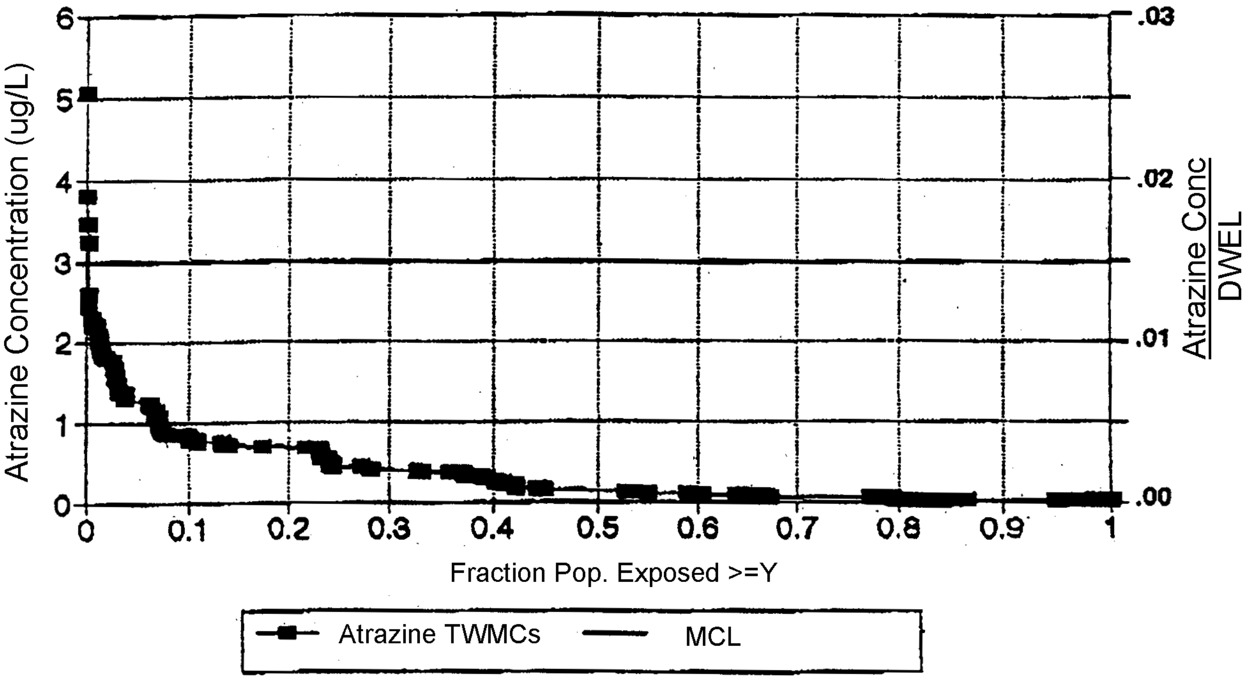


Figure 6

area of interest. Figure 7 illustrates a hypothetical population exceedency curve of the TWMCs of atrazine for the entire population of the United States. Since such curves incorporate many populations with very low drinking water concentrations of atrazine, such as those supplies withdrawn from ground water or from surface waters in areas of little or no atrazine use, the proportions of the population with higher exposures becomes compressed along the left axis, relative to population exceedency curves for atrazine characterizing vulnerable surface water supplies in areas of high use.

For the United States as a whole, the PWMC of atrazine is likely to be less than 0.10 µg/L. Since the relationship between pesticide concentration and cancer risk is thought to be linear at the low risk levels associated with pesticide concentrations (Figure 8)(i.e., the curves are linear, with the slope proportional to the cancer potency factor), the population weighted mean can be used to estimate average cancer risk for the entire area. Given the cancer potency factor estimated for atrazine, and given the assumption that there is no threshold effect for atrazine, (i.e., that any concentration above zero concentration carries with it a cancer risk estimated by atrazine's cancer potency), then the concentration of atrazine which carries with it a 1×10^{-6} lifetime increase in cancer is 0.16µg/L (Figure 9). If the PWMC of atrazine in the United States is 0.10 µg/L, then the average risk from atrazine in drinking water for the United States is 0.63×10^{-6}. This is equivalent to 2.3 additional cancers per year in the entire country of 258,000,000.

The reasonableness of the approach depends greatly on quality of sample, representativeness, sampling interval, etc. OPP should apply appropriate weight to Surface water and ground water estimation given that in most cases the impact of FQPA surface water issues greatly outweighs that of ground water. When considering variability and uncertainty of data, OPP should also take into account the inherent difference in variability of surface water and ground water (GW) (Figure 10). GW tends to be locally spatially variable but temporally relatively constant. On the other hand, surface waters integrate over large watersheds as waters near the watershed outflow but tend to be highly temporally variable (less so in reservoirs).

3) What are the limitations of using CWS and/or natural water raw monitoring data and GIS-based estimates of population exposed for drinking water exposure and risk assessments?

The OPP is strongly urged to seek the pesticide monitoring data developed by the utilities on a quarterly schedule from AWA or other appropriate organizations. For chronic or cancer endpoints of toxicity, such data appear appropriate. For pesticide levels that exhibit autocorrelations between sampling periods, the annualized exposure distributions should incorporate the lag correlations in the model used.

Caution should be exercised with quarterly data. The limitations of such data would be associated with acute endpoints of toxicity; quarterly monitoring potentially might miss episodic exposure situations that may affect not only acute endpoints but could underestimate average exposures used for chronic assessments.

FQPA Dietary Risk Assessment: Drinking Water Component

Combined Monitoring, Modeling and
Relative Risk Approach for Tier 1 Assessments

3.C. Chronic Cancer Risks from atrazine in drinking water

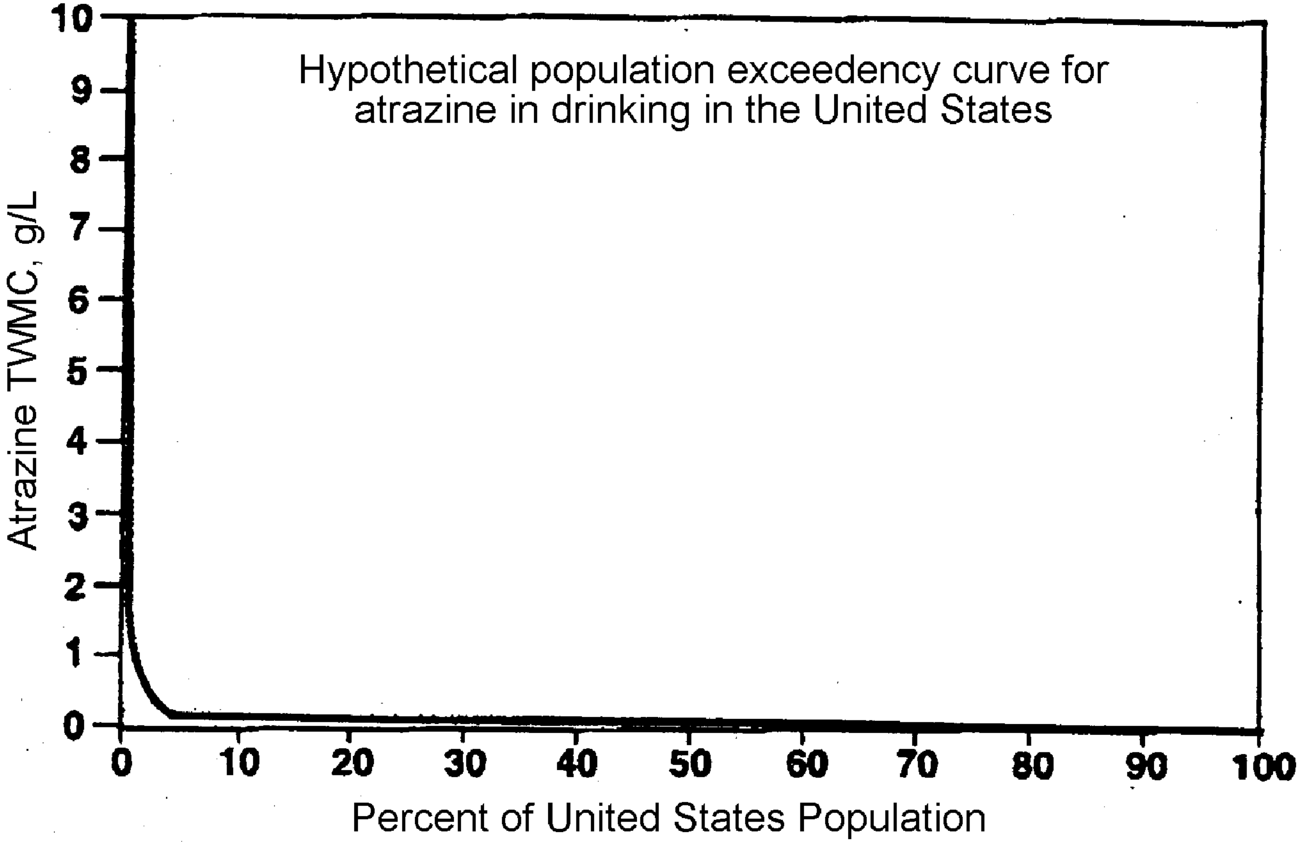
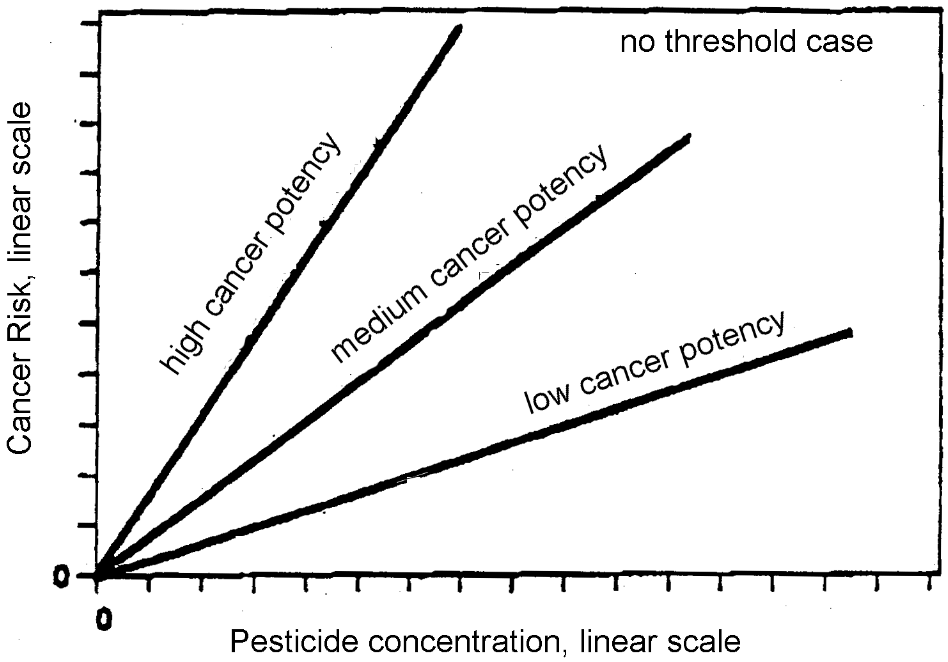


Figure 7

FQPA Dietary Risk Assessment: Drinking Water Component

Combined Monitoring, Modeling and
Relative Risk Approach for Tier 1 Assessments

3.C. Chronic Cancer Risks from atrazine in drinking water



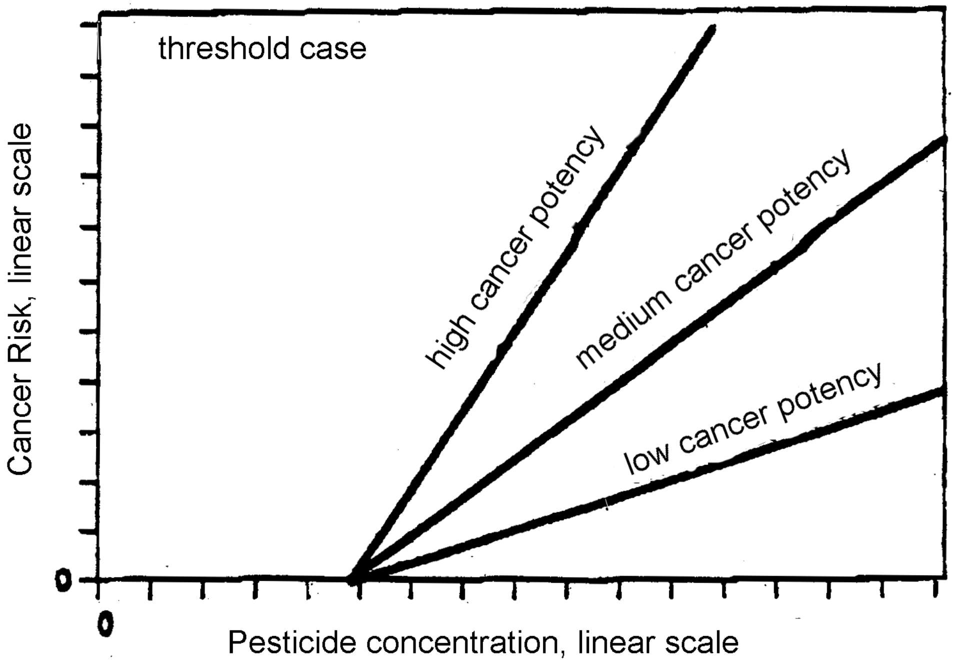


Figure 8

FQPA Dietary Risk Assessment: Drinking Water Component

Combined Monitoring, Modeling and
Relative Risk Approach for Tier 1 Assessments

Conversion of population weighted mean concentration (PWMC) into cancer risk

Atrazine Concentration	**Lifetime Cancer Risk**	**Equivalent Cancers per Year in the United States**
0.16 μg/L	1 x 10^{-6} from Q_1^*	3.7
0.10 μg/L PWMC	0.63 x 10^{-6}	2.3

Figure 9

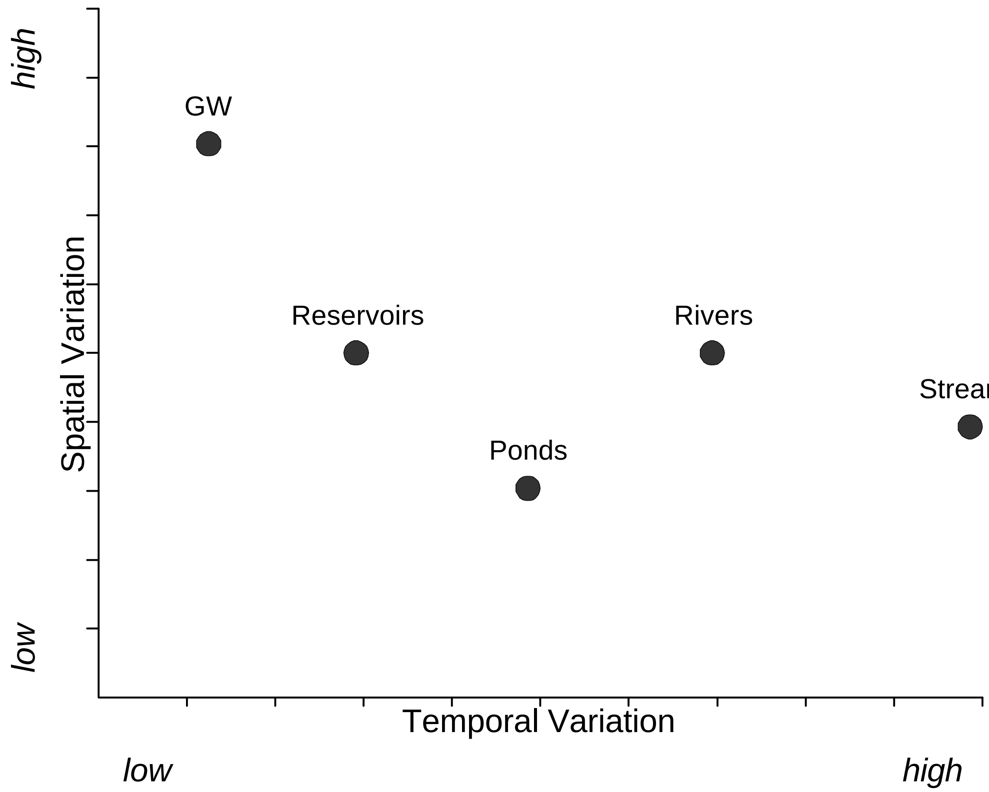


FIGURE 10

Caution is recommended in combining CWS or natural water monitoring data and GIS-based estimates of population exposure. The range of measured values and the mean for a data set can be highly influenced by a bias that results from whether the measurements are representative across all ground water or surface water-based systems. If the frequency and location of sampling is not representative, then the measured values can be unwittingly weighted which distorts the true distribution of pesticide occurrence, and subsequently this distortion is perpetuated in the pesticide exposure distributions.

Using CWS has few limitations, as long as the sampling frequency and other quality control considerations are met. Using natural monitoring data and GIS-based estimates of populations served is useful, but characteristics of individual CWSs should also be considered. In areas of high pesticide applications, more and more CWSs are using some form of treatment to remove pesticides. Consequently, actual exposures are much less than concentrations in the source water. Where water supplies are withdrawn from pumped storage reservoirs, selective (seasonal) pumping of the reservoir can result in much lower pesticide concentrations than the average concentration of the river from which the reservoir is filled.

Solid data are needed on CWS location, water sourcing, population served, upstream watershed size, use of GAC and PAC, sampling regime and frequency, holding time, reservoir depth, historical results, etc.. The AWWA database may be a good place to start. Great care needs to be taken to account for the way many CWSs mix ground water and surface waters at different times of the year. OPP needs to take into account the fact that the screening tools estimate "raw" water concentrations whereas drinking water is frequently treated and the treatment processes reduce the concentrations of some pesticides. Watershed contamination should be addressed more on a local or regional basis, rather than on a national basis, in order to account for weather pattern distributions, cropping pattern distributions and other factors that vary on these scales.

4) What additional precautions beyond those discussed should OPP use in performing and/or reviewing Monte Carlo simulations for exposure assessments?

When performing Monte Carlo simulations, it is recommended that the precision and bias of the exposure assessment be characterized and displayed. The contamination of food prepared in the home and cooked with contaminated drinking water needs to be incorporated into the "integrated" exposure assessments. The assessment should account for this pathway of exposure when using Monte Carlo simulations for developing exposure distributions. Care must be taken to put these data into context.

5) Should OPP address any additional uncertainties in the use of ground and surface water monitoring data for drinking water assessments beyond those discussed?

Some quantitative expression or scientific judgement of the representative nature of the monitoring data needs to be incorporated into the display of total uncertainty (bias in this case) of the assessments. See earlier comments on the need to list all variables and classify them by their ability to make monitoring databases more or less realistic.

6) Does the Panel concur that the most efficient and effective approach to collecting monitoring data (for generating cumulative drinking water exposure assessments for surface water) is to conduct and/or fund multiple residue analyses of samples collected from surface water source CWSs?

OPP should conduct multiple residue analysis of samples collected from CWSs. OPP should plan carefully to ensure that data from this program are useful in answering the questions posed by the program. Data should be collected from a statistically accurate sample of water systems, at appropriate times, and using analytical techniques that are precise and accurate with adequate detection limits. Uncertainties (error) in the monitoring data need to be reported.

While this approach might work in some regions, the Panel recommends that OPP consider a multiple-tier approach using USGS, CWS, small scale studies, revised models, and benchmarking. No single approach is likely to be adequate.

CWS are collecting samples on a quarterly basis. Perhaps the analysis of additional pesticides can be added to those already on their monitoring list, with the caveat that the data are limited to their use for exposure assessments of pesticides that have a chronic or cancer endpoint of toxicity point. Raw and finished water should both be monitored, since systems are removing chemicals using activated carbon, reverse osmosis, etc., and exposure distributions based on only raw water potentially would overestimate exposure in these cases.

Consideration should be given to testing for autocorrelations between quarterly measurements and the use of a model (perhaps a log model if the distribution is log normal) to more accurately estimate the annualized exposure distributions to the pesticides. Simple approaches that proportionally scale monitoring data to obtain annual exposures tend to significantly overestimate the range of distribution.

Pesticide monitoring programs can be used to either characterize the behavior of a pesticide within the environment or to assure the safety of the drinking water supplies or both. For the former, the detection limits must be low enough to see the pesticide within both the high and the low ranges of its occurrence. For the latter, the detection limit can be set at some fraction of the drinking water standard or the total dietary "cupful." For pesticides with low toxicities, these detection limits can be quite high. This could permit the use of lower cost screening tools for the assurance of safety of the drinking water supply. Multi-residue scans cannot provide low detection limits for all of the pesticides of concern.

FOR THE CHAIRPERSON
Certified as an accurate report of the findings:

Larry C. Dorsey
Designated Federal Official
FIFRA/Scientific Advisory Panel
DATE: __________________________

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

SCIENTIFIC ADVISORY PANEL MEETING

A Set of Scientific Issues Being Considered by the Agency in Connection with the Spray-Drift Program

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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 in connection with the Spray Drift Program. The review was conducted in an open meeting held in Arlington, Virginia on December 11, 1997. The meeting was chaired by Dr. Ernest E. McConnell. Other Panel Members present were: Dr. Osman Basaran (Purdue University); Dr. Charles C. Capen (The Ohio State University); Dr. Thomas McKone (University of California); Dr. Karl Mierzejewski (Independent Consultant); Dr. Howard Rockette (University of Pittsburgh); Dr. David Smith (Mississippi State University); Dr. Harold Thistle (USDA Forest Service); Dr. Mary Anna Thrall (Colorado State University); and Dr. Joel T. Walker (University of Arkansas).

Public Notice of the meeting was published in the Federal Register on November 4, 1997.

Oral statements were received from the following:
Mr. David M. Esterly, Dupont Corporation
Robert L. Graney, Ph.D., Bayer Corporation

SPRAY DRIFT TASK FORCE AERIAL FIELD DATA, PHYSICAL PROPERTIES, AND ATOMIZATION STUDIES; AND THE AgDRIFT MODEL

Questions to the Scientific Advisory Panel

OPP poses the following questions to the SAP regarding the aerial field studies, physical properties and atomization data, the AgDRIFT model, and their use in risk assessments:

Aerial Field Studies, Physical Properties and Atomization Data

1. Has the peer review process identified the most important issues that need to be addressed prior to use of the database? Is the Spray Drift Task Force's (SDTF)'s proposal to address these issues adequate? If not, what additional work is needed?

RESPONSE:

In the natural evolution of the data set, the final step (i.e., revision of the data set by the SDTF based on peer review recommendations from the SDTF September, 1997 Data Review Workshop followed by presentation of amendments of the original reports to the Agency and the SAP), had largely been omitted. The SAP (panel) were largely in the position that the EPA had been at the peer review meeting and that few of the alterations had been re-worked by the SDTF, due largely to time constraints.

The SDTF's work in the atomization and aerial spray drift areas has improved the information that is available to the Agency and has the potential to substantially clarify the information available to producers, applicators and extension personnel. The peer review utilized known and respected scientists in the field of applied pesticide application but overlooked experts in other areas as atomization theory, air pollution meteorology, fluid dynamics, computational/experimental fluid mechanics, surface and interfacial phenomena, and rheology (science of flow of non-Newtonian fluids). Even though the peer review membership could have contained a greater representation of specialists to analyze the database, the panel generally concluded that the reviewers chosen were adequate specialists in all subject matters related to review of the database. However, a minority view from the panel also indicated limited confidence of the peer reviewers as specialists to adequately review the database.

The panel raised several issues about the database as noted below. Even though these issues are presented, the majority of the panel concluded that the most critical concerns were identified during the peer review process. However, a minority opinion of the panel was also expressed indicating that several important issues raised by the peer review and SAP processes need to be addressed before AgDRIFT is applicable for regulatory purposes.

- The intent of the Agency is to only consider deposition data, and not the results of the PUF air samplers or vertical card targets. Many of the September 1997 SDTF Data Review Workshop peer reviewers (peer reviewers) had criticized the field study for its choice of collectors which had not sampled the drifting fraction effectively. A peer reviewer described the study as characterizing off-target movement. In addition, the continuous use of the term 'risk assessment' by the Agency implied the importance of small airborne droplets. The peer reviewer pointed out that flat collectors are inherently inefficient collectors of small droplets, and that their efficiency decreases with increasing wind speeds. Given that the whole rationale behind all that had been done to date with the SDTF study was characterization of drift, the panel wanted an explanation of why were such potentially important data being ignored for the present. In addition, the panel also stated that one of the Agency presenters had already highlighted the seemingly inconsistent results obtained in conditions of high wet-bulb depression. In this case, far drift was negatively correlated with increasingly dry conditions. No correlation coefficients were evident. The Agency presenter had surmised that smaller droplets produced under dry conditions were being caught less efficiently by the flat collectors, giving the impression of reduced drift. The Agency presenter added that as a result of the peer review process, the PUF and vertical collector data were being reviewed.

- The AgDRIFT model does not provide any estimates regarding the accuracy of the deposit versus distance curve. The lack of such information gives the user a false sense of security. For example, Yates et al. [Trans. of ASAE 10(5):628-638, 1967] reported predicted deposits and the 95 and 99 % confidence limits for measured drift deposits at several downwind distances. The ratio of the upper 95 % confidence limit to the mean (i.e. predicted) deposits at 83 ft. usually varied from 1.5 to 1.7. At 1304 ft., this ratio varied from about 2 to 3. The lower confidence limits could also be expected to produce these levels of variation.

  In addition to the inherent variation associated with measured drift deposits, the AgDRIFT model should also include variation that is associated with the DropKick model. The DropKick model uses four regression equations (R^2 varied between 0.75 and 0.89) to develop a droplet size distribution curve when using either of three droplet size distribution functions.

  The AgDRIFT output should also reflect confidence limits which were associated with AgDisp. When these three sources of variation are indicated in the output (via AgDRIFT confidence limits), the user can more clearly understand what the output represents. The inclusion of such limits will continually remind the user about the reliability of the estimates the model is generating.

- Panel members differed on the use of either BCPC or VMD as descriptors of different droplet spectra. One panel member stated that the VMD is the 'droplet size' descriptor that is best understood by producers, regulatory personnel, extension workers, researchers, agricultural chemical company employees and aerial applicators. There have been enough other definitions used for generically classifying droplet size distributions that the BCPC system adds to the confusion. Thus, the panel member recommends that 'droplet sizes' be stated as VMDs (i.e. 119, 216, 352 or 464 micrometers for Tier I) and the VMD used for Tiers II & III). However, another panel member commented that BCPC system is a very well judged method of simplifying a complex problem, and is superior to the use of VMDs as descriptors of different droplet spectra.

- The user's manual (p. 79) states that the discharge coefficient was assumed to be 1.0 for all nozzles used in this study. It further states that the continuity equation (i.e. $Q = C_d AV$) is used to set the flow rate for all nozzle types except disc nozzles. For disc nozzles, the manual states that the orifice diameter per se is used to calculate flow rates. Spraying Systems Co. Data Sheet No. 24065 (dated 1987) indicates that the flow rate for a D4 (i.e. 4/64 in. diameter) nozzle @ 40 psi is 0.5 gpm. For the flow rate to be 0.5 gpm, the discharge coefficient (C_d) would have to be 0.68 (i.e. a 32% error in flow rate calculations). Similar calculations for fans nozzles have indicated a C_d of about 0.83. Either the model or the manual should be changed. In any case, the nozzle flow rates being used in the model should correctly reflect actual flow rate measurements.

- The $V < 50$, $V < 141$, $V < 220$ and VMD statistics are numbers that are intended to define the lower part of a given droplet size distribution curve with reasonable accuracy. However, since a statistic like $D_{v0.9}$ (i.e. droplet size at the 90th percentile on the cumulative volume curve) was not included, the upper part of the droplet size distributions could represent substantial error. Conversely, if the VMD approached either 141 or 220, apparently the droplet size distribution would be defined by no more than three of the statistics. Errors on the upper part of the droplet size distribution could substantially alter the fraction of the volume in droplets less than, say, 150 or 200 micrometers. For usual row crop applications (i.e. 8-12 ft. boom heights, wind speeds < 10 mph, etc.), the lack of accuracy for the upper part of the droplet size distribution is apparently not a problem. However, if the model is used with some of its input variables beyond the tested range, droplets in the upper part of the droplet size distribution (not including small droplets) could evaporate and definitely become part of the ‘driftable fraction’.

- Formal uncertainty/variability analysis has not been applied to the database and the resulting models. As a result, the impact of errors and incompleteness in measurements and modeling have not been addressed in the Agency’s presentations or peer review process. Estimating potential ecological exposures to and impacts from pesticide drift and spray drift involves the use of models, measurement data, and the iterative use of models and measurements. Spray-mediated pesticide transport, deposition and contact with aquatic and terrestrial species and the need to represent different populations in different geographical areas can result in large variability and uncertainty in any resulting exposure characterization. The SDTF should undertake additional work to consider the broad issues of dealing with uncertainty and variability in both drift dispersion/deposition and exposure characterization. In addition, there is a need to examine how uncertainty and variability can impact the reliability of either estimated impacts of an unmitigated exposure and the benefits of alternate spray application strategies. The SDTF should be encouraged to continue in their initial efforts to integrate data and model development in the process of producing AgDRIFT.

Although the statistical analyses appeared to be thorough in most instances, some of the common procedures for regression diagnostics are not adequately addressed. Specifically, the impact of influential data points, multicollinearity, errors in measurement and model validation were not systemically addressed. There was also an inadequate assessment of the errors in the estimated estimates given by the models. These would be important in assessing how well the model might perform in other situations. It would be useful to perform validation of the model on independent databases and acceptable performance on a sufficient number of other independent datasets would reduce the urgency of some of the statistical issues presented here. The panel understands that this type of independent verification is planned.

- Phase distribution, that is air/water partitioning, of the pesticide (the so-called secondary transport) was excluded from the SDTF analysis. It is not clear how the Agency arrived at the conclusion that tracking the initial carrier phase (that is the water or oil drops) is more important than tracking the pesticide itself. The Agency did respond during questioning by the panel that they are looking at where the pesticide goes (that is the spray, the pesticide vapor, and the deposited pesticide). However, it is not clear how the spray-drift and vapor transport studies are being integrated. For the purpose of risk assessments, there remains a need to evaluate transport and exposure pathways other than the currently considered direct exposure to spray drift.

- The SDTF should consider “value-of-information” studies. The panel was presented a number of issues that contribute to uncertainty and reliability of estimates made with AgDRIFT. The decision on what to collect and how much to spend to collect new information should be based on the value of new information. In the context of regulatory decision making, the value of information is associated with how much impact that information can have on the decision-making process.

- Studies by the SDTF and others have not addressed the equally important problem of the interaction of the aerosol droplets containing the active ingredients, adjuvants, etc. with the crop/weed surfaces. This is just as important because drops hitting a surface can bounce or break into smaller droplets instead of spreading on and coating that surface. The drops resulting from breakup can lead to further spray drift.

- The effect of evaporation, and in particular the influence of surface active or surfactant species on evaporation, appear to be inadequately understood. Of course, one may adequately separate the problem of atomization from that of evaporation and still be able to make predictions of spray drift.

- Document I94-002 "Drift from Applications with Aerial Sprayers: Integration and Summary of 1992 and 1993 Field Studies" included an analysis of covariance which was conducted to identify factors that address drift while adjusting for selected meteorological conditions. A step-wise regression was also presented which investigates the effect of meteorological conditions on drift. As noted by the peer reviewers, several statistical issues still need to be addressed. The assumptions required in an analysis of covariance need to be justified. In this regard, it may be necessary to use some regression diagnostics and in some cases better adjustment may be attainable with additional terms in the model. The analysis by Environment Canada is encouraging in that similar conditions are obtained, but a different analysis producing the same results is an indirect (and less satisfactory) way of addressing the concerns raised by the peer reviewers.

  As already noted by some of the peer reviewers, the factorial design used for the primary analysis may result in problems of interpretation due to confounding of some factors. In addition, the treatment groups were not presented in the most comprehensible way. Although the California Department of Pesticide Regulation submission summarized some of the issues related to use of the particular factorial design, its is still not clear to what extent the concerns raised in document 14 "Spray Drift Task Force Review" will be addressed. A step-wise regression is not the most appropriate method to investigate the effect of specific variables on an outcome since important variables may be excluded from the model simply because they are highly correlated with other important factors.

- Report I95-003 "The Relationship Between Physical Properties and Atomization: Integration and Summary" presents an investigation of the relationship between physical properties and atomization. Several statistical issues, many already identified by the peer reviewers, still need to be addressed by the Agency. A justification needs to be given for the arcosin transformation and the panel believes that the SDTF has also completed this exercise. There is some indication that multicollinearity may be present and this was not systematically addressed in the report. Although multicollinearity was presented by the EPA, it is still not clear what will be done to address the impact on the prediction equation. As indicated by some of the peer reviewers, the restrictive model needs to be justified. To include a product term only if the main effects are included is reasonable if one wishes to interpret the product term as an interaction. However, if one is trying to obtain the best prediction equation, then a product term can be included without the individual factors. It is important that more information be given on the error associated with the model being used.

- Error bounds were to be provided by the SDTF. However, two issues were not adequately addressed in this regard. First, the independent variables have errors in measurement associated with them which will result in error in the predicted variables as well as potential bias. Such “errors in measurement” were not adequately addressed in the report. In addition, even if the model fits the data on which it was developed, it is not clear how well it will fit an independent data set. Some indication as to how well the model will perform on other data could be obtained by using cross-validation or the PRESS statistic, which is available on some of the standard packages.

- Although the statistical analyses appeared to be thorough in most instances, some of the common procedures for regression diagnostics are not adequately addressed. Specifically, the impact of influential data points, multicollinearity, errors in measurement, and model validation were not systemically addressed. There was also an inadequate assessment of the errors in the estimates given by the models. These would be important in assessing how well the model might perform in other situations. It would be useful to perform validation of the model on independent datasets and acceptable performance on a sufficient number of other independent datasets would reduce the urgency of some of the statistical issues presented here. The panel understands that this type of independent verification is planned.

2. If the SDTF’s preliminary conclusions are upheld by further statistical analysis, does the database validate the generic hypothesis that it is not necessary to know the identity of the pesticidal active ingredient in order to predict droplet-size spectra and, hence, primary spray drift?

RESPONSE:

One panel member suggested that the SDTF's regression equations and reports indicate that the physical properties of the spray has some influence on the droplet size distribution produced. In addition, there are many aerial journal articles which indicate that the physical properties of the spray can affect the droplet size distribution produced by some nozzle types. It appears that the 'physical properties of the spray versus droplet size' issue can most appropriately be addressed by acknowledging that there is some influence and also stating the proportionate contribution of the two groups of variables (i.e. run a sensitivity analysis for the application and tank mix variables). There are likely to be some atomization anomalies which one can't expect any model to handle. For example, Bouse et al. (Trans. of ASAE 33(3), 783-788, 1990) used mixtures of blanks developed for Rely, Whip and Stam. Some combinations of these blank herbicides caused unexpected VMDs based on the physical properties and operating conditions they used. In cases where there seems to be unexpected problems, EPA may need to require some additional atomization tests for those specific sprays. In addition, in the absence of volatility and the source drop size distribution, the panel concludes that the generic hypothesis has been reasonably demonstrated.

However, another panel member indicated that drop size and drop motion are governed by the equations of mass, momentum, and energy conservation. These include the Navier-Stokes or similar equations and the convection-diffusion equation for surfactant transport. These equations have been known for more than 100 years since the times of Rayleigh, Stokes, Bohr, etc. Thus, one absolutely does not need to know the nature of the chemical constituents to predict spray drift. However, one must know with great accuracy and in detail the physical properties of the spray solutions, e.g. shear viscosity, elongational viscosity, dynamic surface tension, etc.

3. Do the physical properties and atomization studies include a sufficient range of values likely to be encountered in agricultural applications in terms of:

a) Adequate and representative numbers of pesticidal active ingredients, formulation types, and use categories?
b) An adequate number of nozzle types in the nozzle studies?
c) Representative operating conditions?
d) Ability to extrapolate wind tunnel measurements to field conditions? If not, what limitations does the SAP see in the current database?

<u>RESPONSE:</u>

The studies were sufficiently broad to encompass most of the more important variables and combinations of variables. The panel agreed with the SDTF selection of a limited range of atomizers for study in the field data. The choice represented a range of droplet spectra, which could be subsequently matched to the much larger range of atomizers studied in the wind tunnel. There are special cases that may need to be addressed in the future.

The panel noted that comments in the peer review indicated that local turbulence effects from propeller wake and control surfaces as well as structures on the aircraft spray system would produce more pronounced shearing effects than would be obtained in the laminar flow conditions of a wind tunnel. Therefore, this would tend to produce smaller droplets than had been obtained in the tunnel for the same nominal airspeeds. Thus, according to the material distributed to the panel, the topic was being empirically evaluated in a wind tunnel study performed by Spray Search. No information was available as to the progress of this study.

The section of the boom affected by the slip stream from the propeller would be where most of the atomization discrepancies might occur. A complex flow field analysis around the aircraft's wing and boom would provide air speed and direction information that could be used to predict droplet size differences. A complex flow field laboratory could assist with such work. A SDTF representative responded to this concern by remarking that this issue was being addressed, but that most likely the effect would be minimal as only small deviations of velocity and airstream angle would be involved.

4. What significant limitations, if any, exist in the aerial field studies in terms of:
- **a) Application equipment (e.g., nozzles, aircraft) and methods?**
- **b) Meteorological conditions (e.g., temperature, humidity, wind speed)?**
- **c) Site conditions (e.g., terrain, crop canopy)?**
- **d) Reliability of deposition data with distance?**

RESPONSE:

The panel stated that it was a monumental task to collect the aerial field data. The investigators made good selection of nozzles and aircraft, etc. to give a range of coverage in the study. However, several limitations were noted as listed below.

- The PUF and vertical card data will likely have limited use. Several studies (experimental or experimental and theoretical) have adequately demonstrated that the deposition efficiency of a static target is a function of the size, spatial position and speed of a droplet as it approaches a target and a characteristic dimension of the target. Thus, many specific targets will have substantially different deposition efficiencies for each droplet size.

- Even though the PUF samplers were directed down (i.e. similar direction as the human nose when the person is in the upright position), previous reviewers have raised several questions about this data set. Another problem that needs to be addressed before the PUF data could be used for inhalation purposes would be the effect of the 'in-out' breathing pattern of humans and animals as compared with constantly drawing air into the PUF samplers. The local flow field around a human's or animal's nose likely differs substantially as compared with the PUF's local flow field. Thus, the flow field will affect the collection efficiency.

- Collector efficiency received attention. First, collector efficiencies must be known to successfully complete the validation. The lack of correlation to humidity casts doubts but the explanation that this lack of correlation is due to collection efficiency is reasonable. The EPA's explanation that the apparent inverse correlation of drift with relative humidity is caused by decreased collection efficiency or smaller dehydrated droplets highlights the importance of applying collection efficiency corrections to the data set. Second, EPA's presentation showed a slide which indicated that the collection efficiency of a flat target increased with increasing wind speed. A panel member pointed out that this was illogical, and that the SDTF document which presented the math behind this figure contained an error, where the length of the flat collector had been substituted for width. In addition, the panel member asked whether flat plate collector data, which was the basis of the validation of the model, had been adjusted for catch efficiency. An SDTF representative responded that they had not been adjusted for catch efficiency.

- The source term must be known exactly. Substantial uncertainty in the source rate (application rate) is disconcerting. Effort should be expended to exactly explain this problem and review the effect on the deposition field. Vague references to tank sampling errors must be made specific and analyzed. If the source rate is not known exactly, the relationships discussed in this work are substantially weakened.

- While the Ag Husky aircraft may be popular in some areas, it is not the predominant aircraft type in many parts of the country. Therefore, the tests which used the Ag Husky as the "standard" could be biased. The industry is rapidly moving to larger, faster, turbine-powered aircraft.

- One panel member suggested that if any field studies are repeated, a mass balance approach to the field study should be considered. However, another panel member did not consider what lands underneath the aircraft as being important. Instead, an essential starting point of any future field study should be the use of collecting media which could give a complete characterization of the spray cloud in terms of its physical dimensions and content.

- A study correlating deposition to various targets/samplers vs. deposition to crops will be very useful and necessary for predicting damage from drift. The deposition on synthetic targets differs from that obtained on real (crop) targets or from inhalation exposure in animals or humans. For purposes of performing meaningful risk assessment and regulation, this study should be planned for the future. The SDTF representative responded that the tank sample data are being analyzed to establish confidence intervals.

- Peer reviewers had criticized the 'spiking' data, in which a known amount of tracer material was placed on a target card so that recovery could be measured. The low spikes had produced inconsistent results, casting doubts on the validity of the far field data.

- The panel asked the agency whether the mismatch between the model predictions and the field data sampled under high wet bulb depression conditions was a result of erroneous predictions by the model or due to poorly caught deposits. In other words, the model prediction could have been correct, and the field data in error, or a combination of the two . The agency presenter agreed that under various conditions it is possible that the model predictions could give more accurate indications of drift than the SDTF field data set.

5. Neither the database nor the AgDRIFT model adequately predict spray drift deposition under stable air (i.e., inversion) conditions. How can stable atmospheric conditions be addressed in the risk assessment and/or application instructions and label restrictions?

<u>RESPONSE:</u>

Most of the aerial drift tests reported by Wes Yates et al. in California were run under stable atmospheric conditions. The studies are considered scientifically sound and state-of-the-art. However, similar to others in the research community, they couldn't afford to run their tests under the strict adherence to GLP. Thus, EPA should consider such studies as part of the aerial field database even though the studies lack exact compliance to GLP guidelines.

Stable atmospheres cause the highest downwind concentrations in many if not most air pollution scenarios. It is disappointing that the SDTF did not address this earlier but it is a reasonable argument that stable conditions may not cause the highest 'total integrated' off-target movement (as opposed to the highest concentration at a point). It is also true that these experiments would require a different study design. The panel suggests developing label language that uses an existing stability classification such as the Pasquill scheme. There is certainly precedent for this choice in other regulatory dispersion modeling.

6. What additional studies, if any, would add significant value to the existing database?

RESPONSE:

The data set that is essentially void in the public domain literature is efficacy data (i.e. dose/response data). These data logically need to be addressed hand-in-hand with the drift data. The near complete void of such data has been documented and reported [Smith, D. B. and R. G. Luttrell. 1997. Chapter 10 Application Technology in The Cotton Foundation Reference Book Series volume III Cotton Insects and Mites: Characterization and Management].

Aerial applicators have been hesitant to substantially increase droplet size for fear of decreasing pest control even though the inert target deposition data typically indicates increasing deposits as droplet size increases. Similarly, the drift models indicate that increasing droplet size will reduce drift deposits. Also, several laboratory and field studies have shown that deposited dosage is the primary application variable related to insect control. Both the weed and insect control literature are nearly void of research where the on-target (i.e. plant or weeds) deposits were measured along with the corresponding pest control. Without the deposit data, we won't learn why one treatment is better or worse than another one.

AgDRIFT Model

1. Is AgDRIFT sufficiently developed to use in risk assessments? If not, what additional work is needed to make this model useful for this purpose?

RESPONSE:

To answer this question, one has to consider the type and quality of information that

AgDRIFT brings to the risk-assessment process. The statistician George Box has made a statement to the effect that "all models are wrong, but some models are useful." One issue to consider first is whether AgDRIFT is useful for risk assessments. Given the current state of the art for pesticide drift studies, it appears that AgDRIFT provides a substantial improvement over existing practice and thus can be considered a "useful" model relative to historical methods. However, relative to the procedures used in risk assessments that are carried out in other EPA programs, AgDRIFT suffers some important weaknesses that should be remedied as the model evolves.

It is not yet clear how AgDRIFT will be used in risk assessments. The implication from the report is that it will be used for both ecological and human health risk assessments. However, for either type of risk assessment, there is a need for more information than that currently exists in the output from AgDRIFT. At present, the models are well suited to characterization of spray drift but the models have not been developed to characterize the transport and fate of the chemicals contained in the spray. The current scientific literature provides overwhelming evidence that above a given Henry's law ratio, chemicals dissolved or contained in droplets can be rapidly stripped off.

Before AgDRIFT can be sufficiently developed for use in risk assessments, there needs to be a better integration of phase transfers in the model system. At a minimum, the model should not be used in situations where the so-called "secondary transport" (that is vapor-phase transport) becomes the primary mechanism by which the pesticide is conveyed from the release to the receptor.

Exposure of humans and ecological receptors to contaminants released to air may occur directly by inhalation and surface contact, indirectly by uptake of contaminants from abiotic media that have been contaminated by atmospheric contact, and by trophic transfer of contaminants that have been accumulated within food webs. Clearly, an attempt to model all direct, indirect, and trophic transfers for all human and non-human species would be impossibly complex.

The panel commented that model predictions should be compared with those of CFD (Computational Fluid Dynamics) codes such as FLUENT, which track individual drops/particles. The EPA responded that some partial studies had been done in Canada. The panel concluded that such studies are not of much use unless they are available in the open literature.

Several peer reviewers have noted that the AgDRIFT predicted deposits and the measured deposits at the more distant locations do not agree. AgDRIFT should be modified so that there is no consistent error between the measured and predicted data. Part of the field tests should be used to revise AgDRIFT and the second part of the data used for verification purposes. A review of the statistical analyses in relationship to the AgDRIFT model indicates there was a comprehensive analysis done on a relatively complex data set. However, AgDRIFT is not a statistical model in terms of regression relationships. Therefore, using data to refine the physical relationships in AgDRIFT may be challenging.

As a final note, future additions of the model should include drop breakup in random/turbulent flow fields.

2. If the issues identified for the DropKick component of AgDRIFT are resolved in a satisfactory manner, does the panel conclude that DropKick is sufficiently developed to use in risk assessments? If not, what additional work is needed to make this model useful for this purpose?

RESPONSE:

Panel members were divided whether DropKick is sufficiently developed to use in risk assessment. Several panel members noted additional research is needed to apply the model for risk assessment purposes.

There is a need to integrate a more formal and quantitative process for dealing with uncertainty and variability. This was one of the primary recommendations of the NAS report Science and Judgment. The model is almost certainly to be used for situations that are outside the range of situations included in the model development process. There is a need to develop a process for informing the user about ranges in which the model results are expected to be most and least relevant. One panel member concluded that there is an inability to determine the accuracy of DropKick and its impact on spray drift deposits based on a lack of confidence limits as discussed previously concerning aerial field data.

If the SDTF has an appropriate atomization data set that was not used to develop DropKick, it would be useful to use the data to help understand the accuracy of the model. If not, the standard deviations from each of the four regression equations could be used to estimate the accuracy of DropKick. An alternative would be to use some of the data in the public domain and compare measured versus predicted (again there is the GLP question). A less desirable alternative would be to compare VMDs from DropKick and any other models in the open literature. In addition, predictions from DropKick should be compared to actual measurement either available to the SDTF or which can be found in the open literature.

Another panel member commented that graphical and statistical information comparing measured and predicted droplet size distribution when using either of the three distribution functions to assess whether the model is useful for risk assessment.

3. Is Tier I in AgDRIFT sufficiently conservative for use as a screening level tool?

RESPONSE:

It is not clear what conservative means - does it mean more likely to overestimate deposition or does it refer to a tendency to overestimate exposure. The Agency holds the assumption that the tendency to over-estimate off-site drift is "conservative". However, in health risk assessment, the concept of "conservative" implies a tendency to overestimate exposure. It is not clear that the tendency to overestimate drift corresponds with a tendency to overestimate exposure (and risk) and there is a likelihood that the tendency to overestimate drift could result in an underestimate (that is a non-conservative estimate) of exposure and risk.

There are a number of factors included in the development of AgDRIFT that tend to increase the estimated concentration and deposition of "spray" to off-site locations as described below:

- The model was validated against field studies on flat terrain with little vegetation.
- A major assumption of AgDRIFT is that the pesticide stays in the spray and that air-borne "spray" concentration is the factor that relates to risk and thus should be estimated in a "conservative" manner. Because it has not yet been demonstrated that this fundamental premise holds, it really cannot be demonstrated at this point how conservative are the Tier 1 results.

- For two calibration chemicals, the SDTF has collected deposition data and developed empirical distributions that can be used to assess the veracity of the multimedia model predictions. This verification framework will be used both to assess model performance and to identify significant data gaps for validated total risk integrated models.

- Tier I in AgDRIFT can be considered a conservative screening tool after it has been modified to: (1) give user choice of mature (3-6 ft.) crop canopy versus short grass or bare ground and; (2) warning that the drift deposits are for neutral or unstable atmospheric conditions. The preferred option would be a choice (stable, neutral, unstable) if stable atmospheric conditions can be shown to cause substantial changes in drift deposits as compared with all other drift variables. Aerial applicators may need additional help with the atmospheric stability issue since burning tires, etc. is not permitted in some locations and interpretation of the smoke from an airplane's smoker may be interpreted differently by different pilots.

4. **What limitations exist in the use of AgDRIFT for risk assessments to:**
   a) Simulate downwind deposition with distance (compared to the field data, AgDRIFT tends to slightly under-predict deposition in the near field and over-predict in the far field)?
   b) Extend beyond the range of application parameters and environmental conditions covered in the field studies?

   <u>RESPONSE:</u>

The question here is what type of risk assessment will AgDRIFT be used for direct contact: with the spray or multipathway contact with the pesticide that has been transported downwind along with the spray or transmitted downwind in a gas phase as a result of volatilization from the spray or from the soil on which it has been deposited.

AgDRIFT (in its present form) should not be used to estimate deposits beyond the maximum distance for which the SDTF made deposit measurements. Additionally, the upper limits of some of the variables in the Users Manual (p. 47) are excessive. For example, swath width = 500 ft., temp = 212^0 F, wind speed = 60 mph, air speed = 400 mph, pressure = 290 psi, boom height = 100 ft. The SDTF data was not anywhere near some of these limits. The limits on the model should be set so that the integrity of the model is maintained. In addition, extrapolations are to be discouraged and if used at all, they should be used VERY judiciously. The model also is not appropriate for long-term effects, re-emission studies, dermal uptake and food web transfers.

It is critical that the model forces the user to change the mechanical system if the flow rate is changed dramatically. There is a physical dependence between flow rate, pressure and droplet size. As an example, drift calculations cannot be correct if the flow rate is doubled without changing the mechanical system specified in the model.

A panel member commented that the over- and under- prediction problem should be rectified before the model is used for risk assessment purposes. The issue of 'pond' deposition versus 'flat card' deposition is of concern especially when one considers the differences in the ambient air flow fields. Small airplanes often drop when they approach larger bodies of water (midday in the summer) due to the downward flow of air. Such 'pond versus bare soil or short grass' air flow field differences should be adequately addressed. The capture efficiency of water versus flat cards also needs to be addressed. The SAP was told that the model presently assumes 100 % deposition efficiency irrespective of the type of target (i.e. human's arms, legs, heads, flat cards, plant leaves. grass, water, etc.). However, another panel member responded that such concerns are not a limitation of AgDRIFT and may be considered irrelevant.

FOR THE CHAIRPERSON:

Certified as an accurate report of findings:

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