Background Paper:
Factoring drinking water exposure into tolerance decisions.

I. **Introduction**

Pesticides are found in both groundwater and surface water throughout the United States. The overall picture emerging from the USGS's initial look at 20 major watersheds in the National Water Quality Assessment Program (NAWQA) is of a mixture of pesticides that typically occur at low levels, punctuated by seasonal pulses of higher concentrations. Ninety-five percent of streams and 50 percent of wells near agricultural and urban areas in the initial 20 study units (spread throughout the United States) contain at least one pesticide and often contain detectable levels of 2 or more. Most groundwater aquifers investigated by NAWQA and about half the streams are sources of drinking water.

Unlike food, which is part of a national distribution system, the water that comes from the tap in a home is for the most part locally derived; if the source of a family's water is contaminated with a pesticide, avoiding exposure can be expensive and difficult. If pesticide levels in a family's drinking water are high, the combined risks from residues on food and residues in water could be significant and could cause health effects. In the United States, roughly 1/2 of the population derives its drinking water from surface water and 1/2 from groundwater, with approximately 15 million households in the United States deriving their drinking water from private wells.

Prior to the enactment of FQPA, OPP's approach to managing pesticides which had the potential to contaminate water was to emphasize prevention; OPP required mitigation measures such as geographic restrictions on use (to protect groundwater) and buffer zones (to protect surface water) to reduce the likelihood of contamination. However, prior to FQPA, human exposure through the drinking water route was not routinely factored into decisions about acceptable levels of pesticide residues on food (i.e., the setting of tolerances).

With the passage of the FQPA, EPA was directed to factor into its human health risk assessment for purposes of setting tolerances, "all anticipated dietary exposures and all other exposures for which there is reliable information". EPA has interpreted this provision as requiring it to factor into its human health risk assessment anticipated exposures to pesticides in drinking water.

Fortunately, not all pesticides have a potential to reach drinking water in concentrations of concern from a human health perspective. The extent to which this pathway of exposure is significant depends on the inherent physical/chemical properties of a pesticide (i.e, properties which are the underlying basis for conclusions about a pesticides' mobility and persistence in soil and water), where and how the pesticide is used, and whether effective treatment of source water occurs prior to ingestion. Some pesticides bind tightly to certain soils, are not very soluble in water, and degrade slowly; others are more soluble but degrade much more rapidly. Still others are not only very soluble in water, but they persist for much longer periods of time. The amount of pesticide used (and where it is used) along with pesticide-specific properties such as its soil binding coefficient(s) and soil degradation ½ life are key factors in determining the likelihood of significant contamination of water.

Although there is much that we do not fully understand about the fate and transport of pesticides in the environment, we have learned a great deal over the past 20 years. The state of the science is such that we are able in most cases to accurately identify (based on use rates, use locations, and fate and transport data and properties) those pesticides which are more or less likely to migrate to and persist in groundwater and surface water. Further, methods developed over the past 5-8 years for estimating pesticide concentrations in surface water for purposes of ecological risk assessment (PRZM/EXAMS and GENEEC) have allowed us to produce some quantitative estimates of pesticide concentrations in small bodies of water. Although OPP has not conducted extensive analyses of the relationship between what these methods predict and what is observed in the real world, the analyses that have been done suggest that these estimates are reasonably accurate for the scenarios simulated (i.e., vulnerable surface water) and function reliably for purposes of an initial screen for ecological risk assessment purposes.

II. **OPP's Approaches to Addressing the FQPA Water Issue**

With the FQPA requirement to factor drinking water exposure into tolerance decisions, and OPP's recognition that "not all pesticides are created equal" with regard to the potential to reach and persist in water, OPP realized that it needed either to have adequate temporal measurements (i.e., measurements over time in a single body of water) and spatial measurements (i.e., measurements throughout entire use areas) of pesticide levels in drinking water or that it needed to be able to estimate pesticide levels in drinking water. We knew that targeted, statistically designed and well conducted drinking water monitoring studies (which could be used to produce probability distributions of contaminant levels) were not generally available, and would never be available in advance of registration for new pesticides. Further, we also knew that gathering the kind of data needed to really "nail down" pesticide levels in drinking water nationally was a resource intensive and time-consuming venture. Because of this, OPP came to the realization that in order to comply with the FQPA it would need to develop methods for estimating pesticide levels in drinking water and methods for analyzing and interpreting available water monitoring data. OPP also realized that developing scientifically sound approaches for accurately estimating human exposure to different pesticides in drinking water would take substantial time and effort.

Interim Approach

In the initial months after the enactment of FQPA (while OPP quickly worked to develop a science-based approach for estimating drinking water exposure) OPP adopted an interim approach which assumed that 10% of what it considered acceptable exposure to a pesticide would occur via the drinking water route (PRN 97-1). That is, OPP reserved 10% of the "risk cup" for water-related risks and allowed food residues to take up to 90% of the "acceptable" risk. This 10% value for drinking water was a "default" assumption that OPP knew was likely to over-estimate actual exposure in many cases, while potentially underestimating actual exposures in some others.

Further evaluation of the "10% default" assumption in light of available information on the measured values of certain pesticides in water revealed that there would be some cases/pesticides where assuming 10% would not be enough to cover actual exposures in drinking water. This fact, combined with the recognition that the Office of Water practice is to assume that as much as 20% of exposure to a pesticide can come from drinking water, led OPP to reconsider its approach. Raising the default to 20% or some other value could be unnecessarily restrictive for many pesticides while still underestimating the drinking water exposure in some cases. Most critically, OPP did not have actual data or scientific principles on which to base such a default assumption.

Current Approach

Based on our experience with the 10% default assumption and our further analysis of available information, OPP adopted the following approach for addressing the "FQPA drinking water issue" in November 1997. This approach, which OPP is continuing to refine, has undergone external scientific peer review by an International Life Sciences Institute (ILSI) panel and the FIFRA Scientific Advisory Panel (SAP).

1. OPP scientists review substantial amounts of registrant-submitted data for each pesticide which describe how the pesticide behaves in the environment. These data tell us whether the pesticide will easily move to groundwater or surface water and whether it will

degrade quickly or persist. Based on these data and pesticide use-related information, OPP scientists draw conclusions about the mobility, persistence, and degradation pathways of the pesticide in soil and water.

2. OPP scientists use these pesticide-specific data as inputs to "screening level" models (GENEEC and PRZM/EXAMS for surface water and SCI-GROW for groundwater). The data used in these models include pesticide-specific data on whether the pesticide has a tendency to bind to soil or move into water, its vapor pressure, how quickly it breaks down in water and soil, and how much is applied. These models allow OPP to develop rough estimates of pesticide concentrations in surface water and groundwater. The models are based on 20 plus years of experience in studying how pesticides move in the environment and are based on a good understanding of the key characteristics of pesticides which determine where they are likely to move in the environment. OPP views the estimates coming out of these models as upper bound estimates of potential pesticide concentrations in drinking water. (*During this stage of the process, OPP also conducts an initial review of in-house water monitoring data to check to be sure that the screening level estimates are in fact "upper bound" estimates. If OPP finds that readily accessible monitoring data suggest the possibility of higher concentrations in surface or groundwater than what these models indicate, then OPP immediately moves to a more thorough analysis of available monitoring data*.)

3. OPP compares the model estimates (i.e., levels which OPP views as upper bound estimates of potential pesticide levels in drinking water) to human health-based "drinking water levels of concern" (which are arrived at *after* having first considered all food-related exposures). Based on this comparison, OPP either clears the pesticide from a drinking water perspective OR it attempts to refine its estimates of pesticide concentrations in order to make them less worst case and more realistic.

4. If OPP determines that it needs to refine its estimates, OPP gathers available water monitoring data and begins its analyses of these data. Typically, OPP consults the United States Geological Survey's (USGS's) National Water-Quality Assessment Program (NAWQA Program) and the National Stream Quality Accounting Network (NASQAN), Office of Water's STORET data base, the data from the USGS's Mid-Continent Group, OPP's Pesticides in Groundwater Data Base, and the National Pesticide Survey to identify monitoring data. In some cases, OPP has also done open literature searches or has contacted state agencies to obtain additional water monitoring data. (*OPP generally defers doing an intensive analysis of available monitoring data until after it completes its*

comparison of the upper bound drinking water estimates to the human health levels of concern because locating, analyzing and interpreting water monitoring data, for purposes of developing a refined estimate of drinking water levels can be very time consuming. In many cases thus far (at least 50% of the cases), OPP's model estimates have been sufficient to clear pesticides from concern and further refinement has not been necessary.)

5. If there are no monitoring data available (or if the available water monitoring data are not adequate for purposes of refining the screening level estimates), OPP makes a risk management decision as to the need for groundwater and/or surface water monitoring and/or risk mitigation.

6. If monitoring data are available and reliable, the scientists in OPP review the data and gather as much information as is readily available on how the samples were collected and analyzed, where they were collected, when they were collected, and why they were collected. OPP attempts to fully characterize the range of values reported, the highest values reported, the 95th percentile value, and the mean value. If the data are adequate to produce some regional-based picture of the distribution of measurements, this is completed as well.

7. After EFED discusses with HED and the risk managers the exposure characterization and how it fits with the specific risk endpoints being addressed by HED, appropriate short-term (for acute effects) and/or longer-term average (for chronic effects or cancer) drinking water concentrations are selected. OPP's analysis and characterization of monitoring data is then incorporated into the food and residential exposure analyses to complete the aggregate exposure assessment.

<u>More on GENEEC (and PRZM/EXAMS) Surface Water Estimates</u>

OPP's decision to use GENEEC and PRZM/EXAMS for purposes of generating conservative upper bound values for purposes of ruling out drinking water (from surface water) as a concern has been the subject of much discussion and misunderstanding. Since November of 1997, OPP has maintained that GENEEC and PRZM/EXAMS are very useful for purposes of rapidly identifying pesticides that are unlikely to occur at significant levels in drinking water derived from surface water. Although OPP views these models and the scenarios it is using as very effective initial screens, it does not believe that it is appropriate to incorporate these values directly into the human health risk assessment for purposes of tolerance reassessment as representative values for the large majority of the U.S. population. OPP believes that further refinement of these values (or confirmation of these estimates through monitoring) is necessary before they should be used in making final decisions in the tolerance reassessment context.

OPP uses GENEEC (which is a meta model of PRZM/EXAMS) to perform an initial screening level assessment of pesticide concentrations in surface water. GENEEC and PRZM/EXAMS were initially used by OPP for purposes of completing ecological risk assessments. These were the only mechanistic models available to OPP for estimating pesticide levels in surface water when FQPA was enacted. GENEEC provides estimates of peak, 96 hour, 21 day and 56 day average pesticide concentrations in a small body of water (20 million liters) at the edge of a 10 hectare treated cotton field under reasonable worst case conditions. Reasonable worst-case means that the compound is assumed to be applied at the maximum label rate, in an environmentally vulnerable setting which is conducive to maximizing the movement of dissolved pesticides to surface water.

Using a pesticide's soil/water partition coefficient and degradation ½ life, GENEEC produces conservative estimates of annual peak and maximum 96-hour, 21-day, and 56-day average dissolved concentrations in a 20 million liter pond, which is assumed to be completely mixed. GENEEC assumes a static, edge-of-field pond (i.e., no buffer) in which inflow from runoff is exactly equal to outflow from evaporation. OPP believes that concentrations estimated in this small pond also represent concentrations which would be likely in a small upland stream in a high use area as well. GENEEC assumes either a single or a series of pesticide applications to bare soil. It simulates a single rainfall event 2 days after the final application and assumes that this single storm washes off into the pond, from 1-10% of the pesticide remaining in the top 1 inch of soil at the time of the storm, depending upon the Koc of the pesticide (i.e., its propensity to move to water or stay with the soil).

PRZM/EXAMS modeling produces slightly refined estimates of potential pesticide levels in surface water, because multiple years are modeled to reflect climatic variations and this modeling is done on a crop specific basis. The advantage of PRZM/EXAMS over GENEEC is that it allows inclusion of more site-specific information in the scenario details regarding application method, temporal distribution with weather, and in general it is better at accomodating the peculiarities of individual chemicals. However, it still represents a small pond or stream from which few people would derive their drinking water.

<u>More on SCI-GROW Groundwater Estimates</u>

OPP developed SCI-GROW as an initial screening level model for estimating pesticide concentrations in ground water under reasonable worst-case conditions, specifically for FQPA purposes. SCI-GROW is an empirical model that links measured field data with measured fate and transport properties of pesticides. It represents a regression of 10 prospective groundwater monitoring studies conducted for OPP by pesticide registrants. The studies were conducted at extremely vulnerable areas (i.e., shallow aquifers, coarse permeable soils, maximum label application rates, with substantial rainfall and/or irrigation to maximize leaching). In each of these 10 prospective studies, the highest 3 consecutive monthly data points from a selected well were averaged to represent 90-day peak average pesticide concentrations. These 90-day peak averages were then regressed against the Relative Intrinsic Leaching Potential (RILP) for 10 pesticides to predict 90-day peak average pesticide concentrations in vulnerable groundwater. The RILPs represent environmental fate properties of the particular pesticides, and are derived from studies which established the degradation ½ lives in soil and soil/water partition coefficients. The monitoring data are normalized by the rate of application.

With data on a pesticides' aerobic soil ½ life and its Koc along with the application rate, OPP is able, using SCI-GROW, to fairly accurately estimate the concentration of a pesticide in shallow groundwater (average depth 15 feet) beneath highly permeable soils (average % sand was 89; average % clay was 4).

<u>More on the Collection, Evaluation, and Interpretation of Available Monitoring Data</u>

In those cases where OPP determines that further refinement is necessary of either the groundwater estimate (from SCI-GROW) or the surface water estimate (from GENEEC and/or PRZM/EXAMS), OPP gathers available water monitoring data and analyzes, characterizes and interprets the data relative to the question being asked by FQPA. That question being, "What are the anticipated human exposures to the pesticide under review via the drinking water route?". By the time a pesticide reaches this stage of OPP's review, OPP scientists are operating under the assumption (based on their review of the battery of fate and transport studies as well as the model results) that the pesticide has some potential to reach surface water and/or groundwater and that it has some potential to be present at levels of concern to human health.

The availability of adequate temporal and spatial monitoring data can reduce much of the uncertainty associated with models, and can provide a more accurate estimate of the distribution of drinking water concentrations in areas of use. In some limited cases, EPA will have "considerable" water monitoring data available to it for a particular pesticide, including small-scale prospective groundwater monitoring studies, state data, USGS data, and, data from the

National Pesticide Survey. Nevertheless, even when available, there are choices to be made over the best use and interpretation of these data, and how to interpret exposures and risk estimates calculated from them. This is particularly true when trying to characterize exposures from a region where there may be more than one source of water monitoring data.

Monitoring studies are are often designed for different purposes, and are often performed under different sampling and analysis protocols, yielding variable detection limits and quality control. Sometimes, the reported limits of detection are significantly above what OPP consider to be levels of concern. Sometimes, there is no clear association between locations sampled and actual areas of use of a pesticide. Such considerations can make filtering and combining data collected under different studies particularly challenging and time consuming.

Sample collection can also be biased in various ways; there are relatively few pesticide samples collected from reservoirs, and alternative data are often collected from sites that are not known drinking water sources. Sampling can also be biased temporally (e.g., samples may be purposefully taken only during certain periods of the month or year), spatially (e.g., samples may be purposefully taken only in certain areas involving certain uses/crops), and by chemical (e.g., samples may only be analyzed for certain pesticides and toxicologically important degradates may not be looked for at all). With flowing water, the timing of sampling can be very critical. Concentrations a few hours or days out of the year can be multiple orders of magnitude higher than during the rest of the year. Without a very intense sampling effort, the maximum concentration can be severely underestimated--which can have significant ramifications if the end point of concern is an acute end point. Over time there can also be a bias in well monitoring towards better quality water since highly contaminated wells may be shut down.

In evaluating, characterizing, and interpreting water monitoring data, EFED attempts to collect as much information as is readily available on the design of the studies. That is, EFED tries to determine (within the very real constraints of time and available resources) how the samples were collected and analyzed, why they were collected and where they were collected. For purposes of completing the FQPA assessment, EFED reviews the reliability/validity of the monitoring data and presents the range of values reported, the highest values reported, the 95th percentile value, and the mean/median values. If EFED has adequate data to produce a regional "picture" of the distribution of reported values, this is completed as well. EFED's characterization of available monitoring data is then sent to HED and to the risk managers.

The next step in the process, OPP's "selection" of a value or values to be incorporated into the human health risk assessment, is heavily laden with policy and, over the past year, has been heavily influenced by the judgement of risk managers in OPP and OPPTS. As is clear from a review of the available monitoring data for CHEMICAL X (see attachment #1) and CHEMICAL Y (see attachment #2), choices need to be made in the selection of drinking water residue estimate(s) from EFED's report on the analysis of available water monitoring data. Sometimes valid reported values vary from one region to another by several orders of magnitude. Without having very specific information on the history of the use of the pesticide in the sampled area, it is very difficult to fully understand the reasons for these differences. In many cases, the number of "non detects" greatly exceeds the number of measurements above the limits of detection--suggesting that generally the pesticide does not move to water and persist. However, this may or may not be true. Because EPA lacks data to verify that reported "non detects" were in actual areas of use, it is often difficult to conclude that the pesticide when used is not, in fact, reaching water. Further, it is not always known whether samples were taken from potable water-that is or could be a drinking water source. Much of the monitoring data are not, in fact, from potable water.

Despite the challenge of analyzing and interpreting these data, and in order to make needed decisions, OPP has felt that it was appropriate to choose a value or values from these data for use in the human health risk assessment. To assume "zero" in the human health risk assessment simply because available, valid monitoring data are variable (making it difficult to select a number or numbers) appears counter to OPP's objective to use the best science available in its decisions. Over the past several months, as OPP has gained experience in reviewing and incorporating monitoring data into tolerance decisionmaking, it has generally chosen "reasonable high end" monitoring values for use in the human health risk assessment. That is, OPP has not selected the highest measured value; but, rather has chosen a value that is "on the high end". Although OPP has developed some crude estimates of the total number of people using different types of source water for drinking water in areas of use, because of data limitations, OPP has not yet been able to develop credible estimates of the number of people expected to be exposed to different concentrations of a pesticide under review to incorporate into its assessment.

IV. Results of Peer Review and External Scientific Review of Our Interim Approach

OPP has sought and obtained external scientific review of its interim approach and of the fundamental aspects of the models it is using for purposes of completing screening level assessments. Most of the external review to date has focused on evaluating the tools and methods OPP is using to estimate pesticide concentrations in drinking water (in the context of these methods serving as initial screens).

ILSI Working Group

In October 1997, ILSI convened a working group of scientists with expertise in the fate, transport, and occurrence of pesticides in surface water and groundwater to evaluate OPP's tools and methods for estimating potential concentrations of pesticides in drinking water. OPP asked the ILSI working group to focus its review on OPP's current methods and models for screening and to recommend improvements which could be implemented in the short term to improve the accuracy of its estimates. OPP also asked for any advice on how to go about refining screening level model estimates and on the use and interpretation of monitoring data.

Regarding the types of information on drinking water that is needed for completing aggregate exposure assessments for FQPA, the ILSI working group recommended in its April 2, 1998 report to EPA that EPA work toward developing probability distributions (as frequency of exceedance) for peak and long term average drinking water concentrations within a pesticide's use region(s). Ideally, the estimates of peak and chronic concentrations should be derived from full temporal distributions in actual drinking water. These are the kind of residue data which are needed for inclusion with the more refined, probabilistic, food-related exposure assessments performed using Monte Carlo methods.

The ILSI working group also concluded that:

1. Screening tools are needed to quickly identify pesticides and pesticide uses that are unlikely to contaminate drinking water AND that, in general, the screening models being used by OPP (i.e., GENEEC and SCI-GROW)

   are of the appropriate type and level of detail to enable the rapid identification of pesticides that are unlikely to be a water problem;

2. Preliminary evaluations indicate that these models may be adequately reliable for screening purposes (although further comparisons of model outputs to measured values is needed to confirm); and

3. The screening models should be improved so that a higher percent of non-problem pesticides (from a drinking water perspective) can be identified in the initial screen.

FIFRA SAP Review

In December 1997 OPP presented for SAP review, its interim methods for estimating exposure to pesticide contaminated drinking water. The FIFRA SAP complimented OPP on the work it had done to develop screening tools while under the severe time pressure to make FQPA decisions. The SAP encouraged OPP to commit to develop a longer term plan to develop improved tools and methods for producing more refined, more accurate estimates of drinking water concentrations. The SAP, responding to specific questions from OPP, provided the following important comments:

1. Many SAP panel members agreed that SCI-GROW generates appropriately conservative estimates of pesticide concentrations in drinking water for use in an initial screen. Most members believed that the estimates needed to be further tested against monitoring data and verified.

2. Nearly all panel members agreed that the pesticide estimates produced by GENEEC are most likely overly conservative and that some adjustments should be made to account for the % cropped area around a water body and the % of that crop treated with the pesticide.

3. OPP needs to develop databases and methods for effectively using monitoring both in assessments and to "validate" model estimates; it needs to invest time and resources in the development of GIS tools related to soil type, crop coverages and water monitoring sampling points; it needs to describe and document all variables in its models and methods and be able to better articulate the relative impact of these variables on its drinking water assessment; and it needs to compare model predictions from its screening models with monitoring data to better understand how these relate.

V. Next Steps to Improve OPP's Drinking Water Assessments

OPP is working with ILSI to hold another working group discussion in the late summer of 1998 to more fully explore what is specifically needed in terms of data and models/tools in order to move forward to conduct probabilistic assessments of drinking water exposure for use in human health risk assessments. This is where OPP ultimately wants to be in the longer term. In addition, OPP's Water Quality Technical Team has developed a draft action plan to respond to the SAP and ILSI recommendations. An important early action item is the development of a drinking water reservoir scenario to replace the small pond scenario currently being used in the running of GENEEC and PRZM/EXAMS. OPP plans to present this modification to the FIFRA SAP at the end of July 1998. Finally, OPP needs to develop interim policy guidance on how it “selects” drinking water residue levels based on monitoring data for use in its human health risk assessments.