Interim Guidance for Conducting Drinking Water Exposure and Risk Assessments

December 2, 1997

This document provides interim guidance in the form of a standard operating procedure (SOP) for preparing drinking water exposure and risk assessments for use in HED's overall aggregate risk assessments. It is accompanied by a flowchart that outlines the process HED and EFED have developed to date as a SOP for the necessary interactions between the two divisions. It describes in detail the processes outlined in OPP's interim drinking water risk assessment policy.

This SOP describes a generic process for performing a drinking water risk assessment for any of the various actions from RD/SRRD to HED/EFED (including REDs, new chemicals, new/amended uses, and Section 18s). The SOP also includes standard ("canned") language to be used in the following situations: 1) when a quantitative risk assessment is not warranted because of use pattern or chemical characteristics, 2) when screening-level models' estimates do not exceed drinking water levels of concern, and 3) when screening-level models' estimates do exceed drinking water levels of concern, but there are no monitoring data to confirm the estimates. All such language is set in italicized typeface and indented. **OGC has commented on and concurred with this language.** As new language is developed for any given scenario, it will be incorporated into the SOP as it is updated. The SOP will evolve over time as HED and EFED refine their risk assessment process for assessing exposure to pesticide residues in drinking water.

EFED's prime responsibility in this process is to develop estimated concentrations of pesticides in drinking water (DWECs) for ground and surface water. All DWECs will be accompanied by basic environmental fate and transport data, e.g., a description of persistence and mobility. If an estimation of DWECs is not possible, EFED will provide a complete explanation regarding deficiencies in the fate and transport data which preclude generation of a model estimate. If necessary, EFED will propose mitigation options as part of the review process to reduce potential impact to drinking waters.

HED will use the ground and surface water DWECs to develop a drinking water exposure assessment that will be incorporated into the overall risk assessment. **The drinking water assessment process should be an iterative process between HED and EFED, where HED drives refinement of the DWEC through an on-going risk assessment process. It is assumed that HED will have refined its dietary (food) exposure and risk assessment to include anticipated residues (using % crop-treated, monitoring and/or field trial data) before requesting refinements of pesticide concentrations in water from EFED.**

Step 1: Initial Meetings for REDs or New Chemicals.

! REDS

For newly assigned REDS, **SRRD initiates a meeting** with members of HED, EFED and BEAD who have been assigned responsibility for their divisions' RED chapter. **The purpose of this meeting is to introduce the responsible staff members from each division to one another and to discuss specific time-lines regarding drinking water assessments.** In addition, use patterns, toxicity issues, degradate/metabolite issues, water issues, and any other major issues affecting the risk assessment are discussed. **SRRD sends a formal request (bean) to EFED** for pesticide concentration estimates in drinking water. **On the beansheet, SRRD indicates the branch in HED working on the RED.** SRRD notes that a bean requesting drinking water numbers has been sent to EFED and includes this action in their RED deliverables check-list.

For REDS in process, **SRRD sends a formal request (bean) to EFED** requesting pesticide concentration estimates in drinking water. Where an initial meeting was not held, HED and EFED need to be proactive and take responsibility for coordinating their RED activities. In general, HED staff will contact the appropriate EFED staff to initiate information exchange relevant to the risk assessment for drinking water. HED staff in RCAB and the reregistration interdisciplinary branches (RRB1 and RRB2) will take responsibility for keeping EFED staff informed of HED's scheduled due dates for RED chapters, presentation dates of their risk assessments to SARCs, and setting up additional follow-up meetings with EFED to discuss drinking water exposure and risk assessments for REDs assigned to them.

Time Frame: ASAP after assignments have been made.

! New Chemicals

RD initiates a new chemical screen meeting after data review packages are sent to HED and EFED for review and after HED and EFED assign team members to the new chemical. **The purpose of the meeting is to introduce HED and EFED team members to one another and to consider the uses associated with the new chemical, and to discuss time-lines for the drinking water assessments.** RD should provide any important use and label information to HED and EFED as soon as possible. **RD sends a formal request (bean) to EFED** for pesticide concentration estimates in drinking water. **On the beansheet, RD indicates the branch in HED working on the action.** HED staff in the registration interdisciplinary branches (RCAB, RAB1, and RAB2) will take responsibility for keeping EFED staff informed of HED's scheduled due dates for risk assessment documents, presentation of their risk assessments to SARCs, and setting up additional follow-up meetings with EFED to discuss drinking water exposure and risk assessments for new chemicals assigned to them.

Time Frame: ASAP after new chemical assignments have been made or HED and EFED have completed their new chemical screens.

! Section 18s

RD sends a bean simultaneously to HED and EFED for the Section 18 action. **RD coordinates the due dates for EFED's assessment with HED's due date** so that HED has time to incorporate EFED's information into their risk assessment, i.e., EFED's memo must be sent to HED a few days prior to HED's due date. RD identifies the branch responsible for the drinking water assessment in EFED and the branch responsible for the risk assessment in HED on each beansheet. Based on this information, EFED sends their finished assessment directly to HED and sends one copy to RD to complete the bean.

EFED develops an abbreviated drinking water assessment with screening-level models using the highest application rate for the pesticide (Steps 3 & 4). The abbreviated assessment includes a statement (1 sentence) regarding persistence and mobility of the pesticide, its soil and water degradates and their half-lives. HED compares the estimated concentrations in drinking water from EFED to back-calculated levels of concern (see Step 5). If the models' estimates are less than HED's levels of concern, HED uses canned language as given in Step 5. If the models' estimates are greater than HED's levels of concern, HED includes this in the risk assessment and notifies RD for a discussion regarding the appropriate action to take. For a Section 18 action, there is not enough time for a complete drinking water assessment using refined models and monitoring data as described below.

! Other Actions

RD uses the same general process, as described above for new chemicals, for new and amended uses, and time-limited tolerances. However, new chemical screen and metabolism committee meetings are not usually necessary. Under FQPA, the entire use pattern of the chemical must be considered, not just the new/amended use or the time-limited tolerance.

Step 2: HED invites EFED to Metabolism Committee Meetings

! **HED takes responsibility for inviting EFED to the HED Metabolism Assessment Review Committee (MARC) meeting** where a decision is made to include or exclude the soil/water degradates in the tolerance expression or risk assessment. EFED should provide a comprehensive fate profile of degradates including identification, patterns of formation and decline in terrestrial and aquatic environments, and relative mobility in soil. Plant/livestock metabolites are compared with soil/water degradates. If HED concludes that any soil/water degradate is of toxicological concern, it should be included in the drinking water exposure assessment. HED informs SRRD/RD of any issues relating to soil/water degradates that may impact the human health risk assessment.

! As soon as possible, HED staff provide the EFED staff with as much information as is available on the selected toxicity endpoints. This will enable EFED and HED to discuss toxicity endpoints relative to available exposure numbers early in the process. This can be done during the MARC meetings.

Step 3: Determine if a Drinking Water Exposure and Risk Assessment are needed

! A drinking water exposure and risk assessment *is not needed* if the use pattern associated with the action meets **either** of the following conditions:

--Active registrations exist for only the following uses: baits, greenhouse uses, seed treatments, potato seed piece treatments, crack and crevice treatments, food handling establishment uses, or other indoor uses. In these cases, EFED states this in a brief memo to HED and completes the bean associated with the initial request for drinking water concentration estimates. EFED copies the memo to RD/SRRD. HED makes a statement such as the following in the risk assessment document:

> *"OPP has considered the registered uses and the available data on persistence and mobility for [chemical]. OPP has determined through a qualitative risk assessment that the use pattern associated with [chemical] [specify use pattern parenthetically] is not expected to impact water resources through labeled uses. In light of this finding, OPP believes that [chemical X's] use will not impact ground water or surface water resources, and therefore is not expected to lead to exposure to humans through drinking water. If new uses are added in the future, OPP will reassess the potential impacts of [chemical] on drinking water as a part of the aggregate risk assessment process.".*

AND/OR

-- EFED determines that the pesticide is neither persistent nor mobile and there is clearly no concern regarding the pesticide's impact on drinking water. In this case, EFED states this in a brief memo to HED, which includes a brief description of the chemical's persistence and mobility characteristics, and completes the bean associated with the initial request for drinking water concentration estimates. EFED copies the memo to RD/SRRD. HED makes a statement such as the following in the risk assessment document:

> *"OPP has considered the registered uses and the available data on persistence and mobility for*

[chemical]. OPP has determined through a qualitative risk assessment that the physical and chemical characteristics of [chemical] are such that it is not expected to impact water resources. [chemical] is neither persistent nor mobile. [Place persistence and mobility characteristics here.] In light of these findings, OPP believes that [chemical X's] use will not impact ground water or surface water resources, and therefore, is not expected to lead to exposure to humans through drinking water. If new uses are added in the future, OPP will reassess the potential impacts of [chemical] on drinking water as a part of the aggregate risk assessment process."

! A drinking water exposure and risk assessment *is needed* if the pesticide is expected to impact water resources, based on usage pattern, persistence and mobility criteria or monitoring data, and thereby could pose a threat to human health through drinking water.

Step 4: EFED provides Drinking Water Estimated Concentrations (DWECs) for Surface and Ground Water to HED

! Once it has been determined that a quantitative drinking water exposure and risk assessment **is needed,** EFED provides estimated concentrations of the pesticide in drinking water (DWECs) and a brief description of the chemical's persistence and mobility to HED. HED will need **maximum and average concentration values** for use in acute and chronic (non-cancer and cancer) exposure and risk assessments, respectively. EFED provides the requested DWECs and persistence and mobility information ASAP in a brief memo and completes the bean associated with the initial request for drinking water estimates. EFED copies the memo to RD/SRRD.

! To provide HED with the required DWECs, EFED initially conducts a screening-level assessment using simulation models (GENEEC for surface water estimates and SCI-GROW for ground water estimates). As a part of a screening-level assessment, EFED also briefly considers available monitoring data from any of a variety of sources. These can include STORET, the Pesticides in Groundwater Database, small-scale prospective groundwater studies, and runoff studies. Results from the monitoring studies are compared to the model estimates to ensure that the models are not underestimating a chemical's potential concentrations in surface and ground waters. Once EFED has verified that the model estimates do not underestimate concentrations reported in ground and surface waters from monitoring data, EFED provides DWECs to HED.

EFED's screening-level assessments with GENEEC and SCI-GRO use the highest labeled application rate for the pesticide to provide worst-case estimates in ground and surface

water. From GENEEC, EFED provides a maximum concentration value, and the 56-day (average) concentration value to HED to be used in surface water assessments. From SCI-GRO, EFED provides one concentration value to be used for ground water assessments. The value from SCI-GRO is considered an upper bound concentration estimate. Because residues of pesticides in ground water do not fluctuate as widely as in surface water, the upper bound estimate is considered adequate for screening-level purposes. Adequate data for a screening-level assessment include all or most of the following: data on the soil and water degradates, solubility, soil-water adsorption coefficients, and rates of decay associated with hydrolysis, soil/water photolysis, and aerobic/anaerobic soil and water degradation processes. [Note: in general, EFED will use GENEEC before using PRZM/EXAMS in a screening assessment. PRZM/EXAMS is a refinement of the GENEEC model].

! If all or a geographic subset of the monitoring data consistently exceed the model values, EFED conducts an in-depth review of the monitoring data and disregards the model estimates. If the monitoring data are judged to be reliable and appropriate for a drinking water assessment, HED uses these data to prepare the required exposure and risk assessments. (See Step 7).

Step 5: HED Calculates Levels of Concern for Drinking Water (DWLOCs) for Comparison against DWECs from GENEEC for Surface Water and SCI-GRO for Ground Water

If the models' estimates do not appear to underestimate a chemical's concentrations in water, HED compares the models' estimates for both surface and ground water to calculated drinking water levels of concern (DWLOCs) for surface and ground water. The DWLOC is the concentration of a chemical in drinking water that would be acceptable as an upper limit in light of *total* aggregate exposure to that chemical from food, water, and non-occupational (residential) sources. Results from a DRES analysis for the chemical are needed before HED can do the back-calculation.

! **For surface water**, HED compares the *maximum concentration estimate* from GENEEC to the DWLOCs calculated for *acute* risk concerns. HED compares the *56-day (average) concentration estimate* from GENEEC to DWLOCs calculated for *chronic (non-cancer and cancer)* risk concerns. [Note: currently the GENEEC model estimated 56-day (average) concentration can be divided by a factor of 3 prior to comparison with the $DWLOC_{chronic}$ and the $DWLOC_{cancer}$. The GENEEC model estimated maximum concentration is compared directly to the $DWLOC_{acute}$.]

! **For ground water**, HED compares the concentration estimate from SCI-GRO to DWLOCs calculated for both *acute* and *chronic* risk concerns. [Note: SCI-GRO model estimates are compared directly to all DWLOCs with no adjustments.]

The $DWLOC_{acute}$ is the concentration in drinking water as a part of the aggregate acute exposure that results in an acceptable MOE. The $DWLOC_{chronic}$ is the concentration in drinking water as a

part of the aggregate chronic exposure that occupies no more than 100% of the RfD. The $DWLOC_{cancer}$ is the concentration in drinking water as a part of the aggregate chronic exposure that results in a negligible cancer risk. Default body weights and consumption values are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child).

! The DWLOC for **acute risk,** is calculated as follows (assuming the NOEL for an acute dietary risk assessment, acute food exposures from an acute DRES run, and the acceptable MOE are known).

$$DWLOC_{acute}\ (ug/L) = \frac{[water\ exposure\ (mg/kg/day)\ x\ (body\ weight)]}{[consumption\ (L)\ x\ 10^{-3}\ mg/ug]}$$

$$where\ water\ exposure\ (mg/kg/day) = \frac{NOEL\ (mg/kg/day)}{MOE} - food\ exposure\ (mg/kg/day)$$

! The DWLOC for **chronic risk** is calculated as follows (assuming the RfD, and food and residential exposures are known).

$$DWLOC_{chronic}\ (ug/L) = \frac{chronic\ water\ exposure\ (mg/kg/day)\ x\ (body\ weight)}{consumption\ (L)\ x\ 10-3\ mg/ug}$$

$$chronic\ water\ exposure\ (mg/kg/day) = [RfD - (chronic\ food + residential\ exposure)\ (mg/kg/day)]$$

! To calculate DWLOC for **cancer risk**, (assuming the RfD or MOE or q*, and food and residential exposures are known),

(A) If the risk is quantified using the **RfD approach**, calculate $DWLOC_{cancer}$ as above under chronic risk.

(B) If the risk is quantified using the **MOE approach**, calculate $DWLOC_{cancer}$ as above under acute risk, except include the chronic food and residential exposures in the aggregate exposure term when calculating the water exposure value.

[NOEL/MOE (mg/kg/day)] - ([chronic food + chronic residential exposure) (mg/kg/day)] = chronic water exposure (mg/kg/day)

© If the risk is quantified using a **q* approach**,

$$DWLOCcancer\ (ug/L) = \frac{[chronic\ water\ exposure\ (mg/kg/day)\ x\ (body\ weight)]}{[consumption\ (L)\ x\ 10^{-3}\ mg/ug]}$$

$$chronic\ water\ exposure\ (mg/kg/day) = \frac{Negligible\ risk}{Q^*} - [(chronic\ food+residential\ exposure)\ (mg/kg/day)]$$

- If the models' estimates (DWECs) are less than HED's levels of concern for drinking water (ground and surface water), HED concludes that the exposure to the pesticide in drinking water is insignificant, and the associated human health risks are not of concern. **Qualitative risk language should be used to characterize the risk.**

- The following standard language provides an example of qualitative risk language for a **pesticide with food uses, but no residential uses**, for which acute and chronic (RfD and cancer (q*)) risk assessments are required, and where the estimated concentrations in drinking water are less than HED's levels of concern for all risk assessments required.

> *"OPP has calculated drinking water levels of concern (DWLOCs) for acute exposure to [chemical] in surface and ground water for [subpopulations]. They are [X, Y, ...] ppb, respectively. For chronic*

(non-cancer) exposure to [chemical] in surface and ground water, the drinking water levels of concern are [X, Y,...] ppb for [subpopulations], respectively. For chronic (cancer) exposure to [chemical] in surface and ground water, the drinking water levels of concern are [X, Y,...] ppb, respectively for [subpopulations]. To calculate the DWLOC for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure (from the DRES analysis) was subtracted from the ratio of the acute NOEL (used for acute dietary assessments) to the "acceptable" MOE for aggregate exposure to obtain the acceptable acute exposure to [chemical] in drinking water. To calculate the DWLOC for chronic (non-cancer) exposure relative to a chronic toxicity endpoint, the chronic dietary food exposure (from DRES) was subtracted from the RfD to obtain the acceptable chronic (non-cancer) exposure to [chemical] in drinking water. To calculate the DWLOC for chronic exposures relative to a carcinogenic toxicity endpoint, the chronic (cancer) dietary food exposure (from the DRES analysis) was subtracted from the ratio of the negligible cancer risk to the q to obtain the acceptable chronic (cancer) exposure to [chemical] in drinking water. DWLOCs were then calculated using default body weights and drinking water consumption figures.*

Estimated maximum concentrations of [chemical] in surface and ground water are [X] and [Y] ppb, respectively. Estimated average concentrations of [chemical] in surface and ground water are [X] and [Y] ppb, respectively. [Note: For the purposes of the screening-level assessment, the maximum and average concentrations in ground water are not believed to vary significantly.] The maximum estimated concentrations of [chemical] in surface and ground water are less than OPP's levels of concern for [chemical] in drinking water as a contribution to acute aggregate exposure. The estimated average concentrations of [chemical] in surface and ground water are less than OPP's levels of concern for [chemical] in drinking water as a contribution to chronic aggregate exposure. Therefore, taking into account the present uses and uses proposed in this action, OPP concludes with reasonable certainty that residues of [chemical] in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time.

OPP bases this determination on a comparison of estimated concentrations of [chemical] in surface waters and ground waters to back-calculated "levels of concern" for [chemical] in drinking water. These levels of concern in drinking water were determined after OPP has considered all other non-occupational human exposures for which it has reliable data, including all current uses, and uses considered in this

action. The estimates of [chemical] in surface and ground waters are derived from water quality models that use conservative assumptions (health-protective) regarding the pesticide transport from the point of application to surface and ground water. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of concern in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of [chemical] on drinking water as a part of the aggregate risk assessment process.

! If the models' estimates (DWECs) are greater than HED's levels of concern for drinking water (DWLOCs) from ground and surface water, HED notifies SRRD/RD that a refined assessment from EFED is needed. **HED initiates a meeting with EFED and invites RD/SRRD to discuss the necessary refinement**. **HED sends a subbean to EFED** requesting the refined assessment. The instructions portion of the beansheet will include HED's calculated DWLOCs for EFED's use, and any specific details about the refined estimate of concentrations in drinking water as discussed by EFED and HED. For surface water, EFED may choose initially to conduct a refined model assessment. For ground water, EFED will search for monitoring data to refine the assessment.

Step 6: EFED Conducts a Refined Modeling Assessment

! For surface water, when the GENEEC model estimate is three times greater than the $DWLOC_{cancer}$/ $DWLOC_{chronic}$ or when the estimate is greater than the $DWLOC_{acute}$, EFED refines the GENEEC estimate using the PRZM/EXAMS model. **EFED provides a 1- in- 10 year maximum and a 1- in- 10 year annual average concentration estimate from PRZM/EXAMS of the pesticide in surface water to HED, and HED compares the refined model estimate to DWLOCs as above**. [Note: PRZM/EXAMS model estimates are compared directly to the DWLOCs with no adjustment.] If the refined model estimates are lower than the DWLOCs, HED uses the same language as above (Step 5) for a qualitative risk assessment, and EFED completes the bean associated with the request for refined estimates of drinking water numbers.

! If the refined surface water model estimates (DWECs) are still greater than HED's levels of concern for drinking water (DWLOCs), HED again notifies EFED, and EFED conducts a detailed review and analysis of all available monitoring data, and determines if they are reliable and appropriate to use for an assessment of the pesticide's impacts on drinking water. HED does not send another bean to request continued refinement of the drinking water numbers. EFED uses the bean sent to request the initial refinement of the drinking water concentration estimates until the drinking water estimates are as refined as possible.

! For ground water, a refined model is not yet available. EFED will review all monitoring data to determine if they are appropriate for a human health exposure and risk assessment.

Step 7: EFED and HED Work Together to Characterize Monitoring Data for use in HED Risk Assessments and **HED Prepares a Quantitative Exposure and Risk Assessment**

! Once EFED determines the appropriateness and reliability of available ground and surface water monitoring data, **EFED meets with HED** to discuss the characterization of the water monitoring data with respect to a human health risk assessment. RD/SRRD should be invited to these meetings. If the data are suitable, EFED provides maximum and annual average concentrations from monitoring data for all regions/states/counties for which monitoring data are available, appropriate, and reliable.

! EFED provides the concentrations requested and characterizes the monitoring data in a memo to HED, and completes the bean associated with the request for a refinement of drinking water estimates. The characterization includes as much of the following information as possible:

-- Source of Data (STORET, Pesticides in Groundwater Database, USGS, other)

-- Location of monitoring (the region/state/county where samples were taken, and an indication as to whether the monitoring data is for ground or surface water, and whether or not it represents drinking water sources or ambient water quality)

-- Sampling Dates

-- Total Number of Samples Analyzed

-- Total Number of Samples with Detects

-- The maximum concentration, and the average annual concentrations, and the range of concentrations.

-- Limits of Detection (LOD) and Limits of Quantification (LOQ)

-- Spatial overlap of monitoring data with potential use areas

-- Depth of well water sampled for ground-water monitoring

-- Water sources (lake, river, stream, etc.) For surface-water monitoring

-- A clear statement regarding the level of confidence in monitoring data (the confidence level associated with the monitoring data, i.e., high, medium or low),

-- A statement regarding what the monitoring data represent (e.g., an upper bound, lower bound, or something in between).

-- Estimates of populations living in the areas sampled.

! HED prepares a **quantitative** exposure and risk assessment using the monitoring data provided by EFED. HED calculates the drinking water **exposure** using values from EFED in the following equations:

$$\text{Exposure (mg/kg/day)} = \frac{\text{concentration water (µg/L)} \times 10^{-3} \text{ (mg/µg)} \times 2 \text{ L/day}}{70 \text{ kg for adults (male)}}$$

$$\text{Exposure (mg/kg/day)} = \frac{\text{concentration water (µg/L)} \times 10^{-3} \text{ (mg/µg)} \times 2 \text{ L/day}}{60 \text{ kg for adults (female)}}$$

$$\text{Exposure (mg/kg/day)} = \frac{\text{concentration water (µg/L)} \times 10^{-3} \text{ (mg/µg)} \times 1 \text{ L/day}}{10 \text{ kg for children}}$$

! For acute exposure calculations, HED uses maximum concentration values for surface and ground water from EFED. For chronic (cancer and non-cancer) exposure calculations, EFED uses average annual concentration values for surface and ground water from EFED.

! HED calculates the **aggregate risk** using the exposure values calculated above for ground and surface water, separately, to account for the drinking water exposure in the aggregate risk equations provided in HED's "Interim Guidance for Conducting Aggregate Exposure and Risk Assessments". (T: drive under $SOP).

! **HED characterizes the drinking water exposure in light of EFED's characterization of the data and confirms their understanding of the characterization with EFED.** HED indicates if the monitoring data represent drinking water or ambient water quality, and if pesticide use is associated with the areas monitored. HED states the level of confidence in the data. HED states if the calculated risk is associated with a specific

region or regions of the country or a specific state or states. If population estimates are provided for specific regional monitoring data, HED discusses exposure in terms of population.

! If the aggregate risk inclusive of drinking water exposure is acceptable, HED finalizes its risk characterization. **If the aggregate risk is unacceptable, and HED has refined its dietary exposure as much as possible, HED meets with EFED and SRRD/RD to develop risk mitigation.** Step 9 provides some direction in developing the appropriate risk mitigation response. In general, chemicals needing risk mitigation will be handled on a case-by-case basis.

Step 8: EFED's Model Estimates Exceed HED's Levels of Concern AND No Monitoring Data are Available.

! If the models' estimates (DWECs) are higher than HED's levels of concern, **and** adequate monitoring data **<u>are not</u>** available to EFED, interim risk management and monitoring data may be required as a part of reregistration for RED chemicals, as a condition of registration for new chemicals, or as a condition of extending a tolerance or adding a new use. Step 9 provides some direction in developing the appropriate risk mitigation response. In general, chemicals needing risk mitigation will be handled on a case-by-case basis.

Step 9: Interim Risk Management

Interim risk management relative to drinking water will be needed in either of the following cases:

! When an unacceptable risk results, and drinking water exposure contributes significantly as documented by monitoring data, **HED, EFED and SRRD/RD meet to consider** risk mitigation. Mitigation may include: drinking water monitoring requirements, establishing buffer zones, application rate and use reduction, and cancellation of use in regions driving the unacceptable risks.

! When estimated concentrations in drinking water (from screening models) exceed levels of concern, and there is no available monitoring data, **HED ensures that the food risk is as refined as possible, and EFED likewise ensures that the model estimate is as refined as possible. HED, EFED and SRRD/RD meet to consider the entire 'risk cup" picture** for the pesticide before deciding on how to manage the risk. This meeting should include the respective HED and EFED branch chiefs or branch senior scientists and the appropriate staff. In the meeting, the appropriate risk mitigation measures are determined. Factors affecting their decision would include:

1) How full is the risk cup from food residues (and residential uses if applicable)?

2) How refined are the risk estimates for food residues (and residential uses if applicable)?
3) The nature of the endpoint on which the DWLOC is based.
4) The total quantity of the pesticide use, i.e., how widespread is its use pattern?
5) The potential for residues in drinking water to cause the risk cup to "overflow", and the potential magnitude of the overflow.

An example of a theoretical risk decisions made during such a meeting are given below:

If 85% of the risk cup for a reregistration chemical is filled with food and non-occupational (residential) uses, and the dietary risk estimate is as refined as it can be, and the toxicological endpoint is a serious developmental concern, and the PRZM/EXAMS and SCI-GROW model estimates are significantly greater than the DWLOC, then a risk management decision may include cancellation or restriction of use in vulnerable areas, a reduction in uses to reduce food-related exposures and/or a similar action for residential uses while surface or ground water monitoring is conducted to confirm the chemical's concentrations in water.

In contrast, if the PRZM/EXAMS estimate or the SCI-GROW estimate was only slightly greater than the DWLOC, then the risk management decision could include reductions in application rates or the establishment of buffer zones while surface and ground water monitoring is conducted.

! Specific canned language for the above scenarios is not likely to be useful. HED must describe each risk cup situation individually including consideration of the points listed above. The exposure to the pesticide in drinking water need not be quantified in the risk assessment; however, we need to qualitatively describe our level of concern regarding the potential risk from exposure to the chemical in drinking water (e.g., is the model estimate orders of magnitude greater than the drinking water level of concern or only a fraction higher). If risk mitigation measures are pursued, there must be an explanation of how those measures are expected to reduce potential exposure, and therefore risk, in the interim while monitoring data are collected. **RD/SRRD must then decide on how to proceed in the face of uncertain exposure and risk for drinking water**.