Science Policy Notice

SPN2004-01

Estimating the Water Component of a Dietary Exposure Assessment

This document provides an overview of the policy of Health Canada's Pest Management Regulatory Agency in estimating the concentration of pesticides in potential drinking water sources. These estimates are incorporated into aggregate exposure assessments as part of the process of assessing the potential impact of pesticide use on the health of Canadians. The types of models and the general approach being used by the Agency for estimating pesticide concentrations in potential drinking water sources are described. In addition, the importance of monitoring data and water treatment is discussed.

This document replaces Regulatory Proposal PRO2003-01 published for public comment in March 2003. Comments received were taken into consideration.

(publié aussi en français)

30 April 2004

Health Canada Santé Canada

Canada

Executive Summary

Health Canada's Pest Management Regulatory Agency (PMRA) estimates the concentration of pesticides in potential drinking water sources and incorporates these estimates into aggregate exposure assessments as part of the process of determining the potential impact of pesticide use on the health of Canadians.

Canadians use both surface water and groundwater for drinking; consequently, for its drinking water assessments, the Agency estimates pesticide concentrations in both these sources of drinking water. The PMRA uses a tiered approach for exposure modelling that consists of progressive levels of refinement. This framework is consistent with that used in the United States. The Level 1 assessment (initial level of assessment) is designed to efficiently screen out pesticides that do not pose any drinking water concerns. If the Level 1 assessment results in an acceptable exposure estimate, then the pesticide passes the screen and no further assessment is necessary. However, if the Level 1 assessment results in a drinking water concentration that represents an unacceptable exposure, then a more refined Level 2 assessment is undertaken based on the use pattern and/or refined input parameters. The same tiered approach is used for both new pesticides and those undergoing re-evaluation.

The Agency uses exposure models to estimate concentrations of pesticides in both surface water and groundwater. For surface water, the PMRA uses the linked PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modelling System) models. Pesticide concentrations in surface water are modelled in two types of vulnerable drinking water sources. The first is an index reservoir that is also used by the United States Environmental Protection Agency (USEPA) in its exposure assessments. The second potential source is a prairie dugout that is included in addition to the reservoir when pesticides are to be used in the prairie provinces. Pesticide concentrations in groundwater are estimated using the LEACHM model (Leaching Estimation and Chemistry Model). LEACHM simulates pesticide movement through a soil profile and into shallow groundwater.

For both surface water and groundwater modelling, the PMRA has developed a series of agricultural scenarios that are typical of many of the major crop growing areas in Canada. Inputs for these scenarios include realistic data on the weather, soil, crops and hydrology.

In addition to modelling, the Agency considers available pesticide monitoring data for potential drinking water sources. In Canada, however, there is a paucity of valid pesticide monitoring information that can be used in the risk assessment. The Agency is pursuing opportunities to develop high-quality national scale monitoring data with the provinces, territories and municipalities, as well as other federal departments.

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1.0   Introduction

Under the *Pest Control Products Act*, the PMRA has the responsibility to protect the health of Canadians from unacceptable risks associated with pesticide use. In order to assess potential risks of pesticide use to the health of Canadians, the Agency must be able to estimate their potential exposure to pesticides and any pesticide transformation products that might be of toxicological concern. The exposure assessment must be comprehensive and include potential pesticide exposure from all sources and by all routes (aggregate exposure[1]). Estimating potential exposure to pesticide residues in sources of drinking water is an important part of the dietary exposure assessment.

Pesticides are used throughout Canada and there are many potential pathways by which they may find their way into drinking water sources. In Canada, both surface waters and groundwater are used as sources of drinking water, and pesticide use patterns are such that contamination of these sources may occur via drift, runoff or leaching through the soil.

In the past, the PMRA estimated pesticide concentrations in surface waters only. These estimates were often not very realistic because the models used were simplistic and the model inputs were very conservative. The PMRA is now in the process of developing a more comprehensive approach to estimating the concentration of these compounds in surface and groundwater sources of drinking water. An overview of this new systematic approach is described in this document.

2.0   Current approaches in other jurisdictions

Both the United States (U.S.) and the European Union (EU) estimate expected environmental concentrations (EECs) of pesticides in surface water and groundwater as part of their risk assessment processes (FOCUS, 1995; FOCUS, 1997; FOCUS, 2000; USEPA, 1999). In the U.S., the EECs are estimated and aggregated with estimates of food exposure and residential exposure to produce an aggregate exposure and risk assessment. In the EU, the EECs are not incorporated into an aggregate assessment. Instead, they are compared with the legislated maximum allowable concentrations in drinking water sources that "can be consumed safely on a life-long basis" (Council Directive 98/83/EC, 1998).

Both these jurisdictions use a tiered approach to estimate pesticide concentrations in drinking water sources. Initial tiers consist of using screening level models with conservative inputs to rapidly screen out pesticides that will probably not pose a concern with respect to drinking water. In its initial screening level assessment, the USEPA uses models that simulate generic conservative scenarios to estimate EECs in groundwater and

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[1]   Aggregate exposure refers to exposure to a single chemical by multiple pathways (through food, drinking water and residential use) and routes of exposure (oral, dermal and inhalation).

surface water. If the estimated concentration exceeds the drinking water level of comparison (DWLOC[2]), the pesticide fails the screen and moves to the next tier of assessment. Higher tiers of assessment may include the use of more refined modelling techniques or available monitoring data, and may require that additional laboratory and/or field studies be conducted by the registrant. The rationale behind this approach is that the initial tiers are less resource intensive and therefore allow "safe" chemicals to be identified and screened out with a minimal input of resources (both monetary and human). For a Tier 2 surface water assessment, the USEPA uses an agricultural scenario based approach. The USEPA does not currently conduct Tier 2 modelling when groundwater concerns are identified, but instead requests monitoring studies. In contrast, the EU conducts groundwater modelling using robust models with regional agricultural scenarios at the outset of its analysis.

3.0 PMRA approach for estimating drinking water concentrations

Close to 75% of the residents of Canadian municipalities with populations exceeding 1000 receive their drinking water exclusively from surface water sources, and the remaining 25% receive their water either exclusively from groundwater or from a combination of groundwater and surface water (Figure 1). Consequently, it is essential to estimate pesticide concentrations (including transformation products of toxicological concern) in both groundwater and surface water sources.

The PMRA estimates pesticide concentrations in both surface water and groundwater sources using a tiered approach. The intent of the tiered approach is to efficiently screen out pesticides that do not pose any drinking water concerns and focus more resources on those pesticides that may present a potential concern in drinking water. A Level 1 assessment is the screen that provides a conservative estimate of pesticide concentrations in potential sources of drinking water. If a pesticide passes the Level 1 assessment, no further assessment is necessary. Conversely, if the Level 1 assessment produces a drinking water concentration that represents an unacceptable exposure, then a more refined Level 2 assessment is undertaken. This general framework is similar to that used by the USEPA.

As part of the assessment process, the PMRA uses established computer models to estimate pesticide concentrations in both surface water and groundwater sources of drinking water. The input parameters for these models include data from experimental studies (physical/chemical properties and environmental fate characteristics of the pesticide), Canadian weather stations (site-specific rainfall and temperature), Canadian soil surveys (site-specific soil properties) and the product label (application rates and frequencies).

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[2]   The DWLOC is the highest concentration of a pesticide in drinking water that would be acceptable considering the toxicity profile of the pesticide and the estimated exposure to that pesticide from all other sources (i.e., food and residential uses). Both acute and chronic DWLOCs are considered.
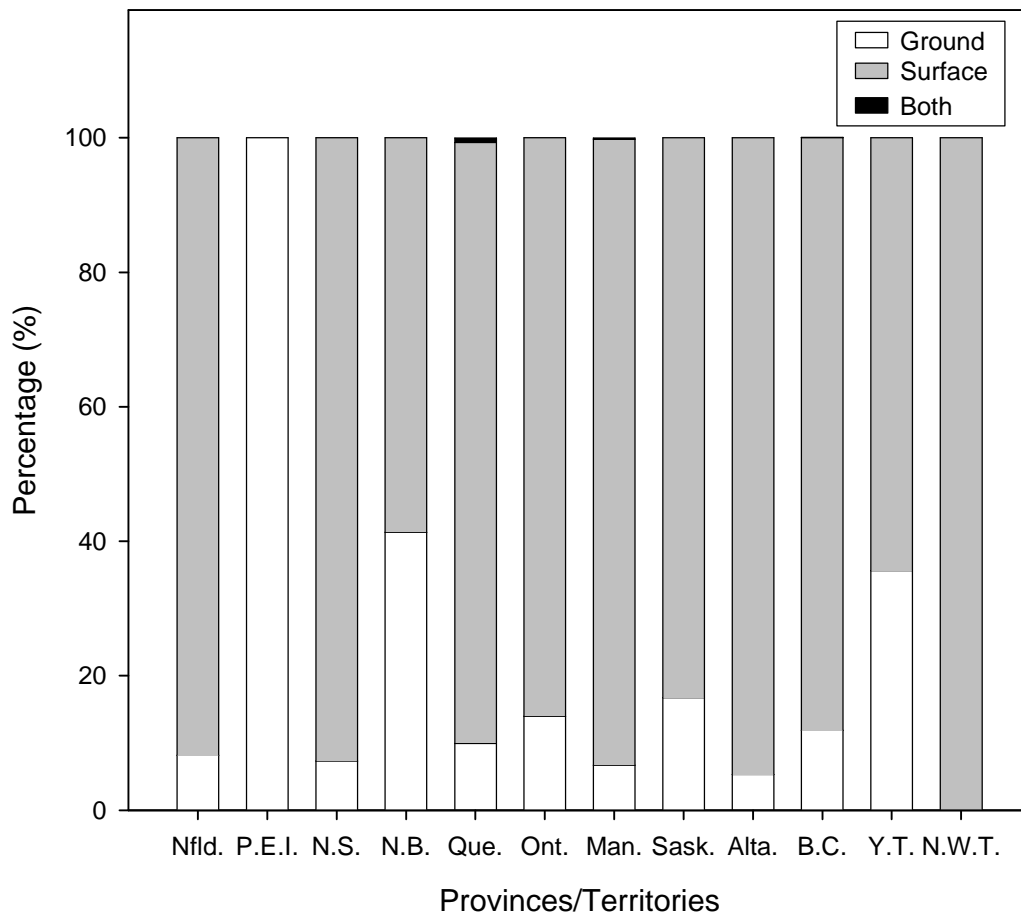
Figure 1 **Percentage of water from groundwater and surface water sources supplied to residents of Canadian municipalities with populations exceeding 1000 [generated from the 1999 Environment Canada Municipal (Water) Use Database]**

In general, the Level 1 estimates use real soil, weather and plant growth related information along with the following conservative chemical fate characteristics and pesticide application information:

- **Fate characteristics of the chemical**
    a.   Longest half-lives[3] in environmental media (e.g., soil, water) where multiple values exist
    b.   Smallest K_{oc} and K_d coefficients where multiple values exist[4]

- **Assumptions about use**
    a.   Highest label rate of application
    b.   Maximum number of applications per year
    c.   Shortest time interval between applications
    d.   The pesticide is applied every year of the simulation
    e.   100% of the watershed is assumed to be cropped
    f.   100% of the crop is assumed to be treated with pesticide

In a Level 1 assessment, a number of scenarios representing different agricultural regions across Canada are simulated (see Section 3.1). The scenario producing the highest EECs is selected, thereby ensuring that the risk assessment is protective of a range of conditions. The PMRA, however, recognizes that at some locations, actual pesticide concentrations in surface water or groundwater can be lower than the model estimates. This is especially true in a Level 1 assessment. For example, although users could apply a pesticide at the highest rate and frequency allowed on a product label, typical use rates and frequencies can be lower than the input values for application rate used in the model. While not required by the pesticide label, users may also engage in practices that may reduce pesticide runoff or leaching (e.g., soil-incorporation of the pesticide, the use of "no-application" zones or filter strips around water bodies, not applying in areas where water table is shallow, or not applying when weather conditions favour leaching).

A Level 1 assessment resulting in unacceptable pesticide concentrations in sources of drinking water advances to a Level 2 assessment. The PMRA takes a pesticide-specific approach to refining the Level 1 drinking water estimate. In a Level 2 assessment, the Agency may undertake any or all of the following: use input parameters that more accurately reflect the use pattern of the chemical in question (e.g., select the most appropriate chemical fate characteristics based on the use pattern instead of using the most conservative value); restrict the modelling to scenarios that reflect the current or proposed uses of the pesticide; consider monitoring data; use accurate percent cropped

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[3]   Half-life refers to the amount of time it takes for 50% of the pesticide to transform in the environment.

[4] K_d is the soil–water partition coefficient, defined as the ratio of the chemical concentration in the solid phase to the chemical concentration in the surrounding aqueous solution. $K_{oc} = 100\ K_d\ /$ % organic carbon. Both coefficients are used to predict the mobility of chemicals.

area when available; and, request additional studies. Registrants will be contacted to obtain any of this relevant information on the parent or transformation product(s), if needed.

3.1 Agricultural scenarios

In its water models, the PMRA uses a series of agricultural scenarios that are representative of areas of major agricultural activity and the important crops grown. The scenarios were developed by Environment Canada as part of an Expert System for Pesticide Regulatory Evaluations and Simulations (EXPRES) (Mutch et al., 1993). Each scenario within the EXPRES database contains detailed information on soil properties (chemical, physical and hydrological), crop parameters, agricultural practices and daily weather data from relevant Canadian weather stations.

The PMRA is currently using 11 of the EXPRES agricultural scenarios in its drinking water assessment. They include scenarios representative of the lower Fraser River Valley, British Columbia (raspberry); the Okanagan Valley, British Columbia (orchard); the Peace River district, Alberta (barley); southern Alberta (sugar beet); southern Saskatchewan (wheat); Manitoba (potato—currently for surface water only), southwestern Ontario (corn), the Niagara region, Ontario (vineyard); the Yamaska River Valley, Quebec (corn); Prince Edward Island (potato); and the Annapolis Valley of Nova Scotia (apple). An additional 12 scenarios available from EXPRES are being considered for inclusion in this process.

In developing each scenario, it was recognized that a range of soil and climatic conditions exists in each geographic region. The soil and climatic conditions selected for the model input files are typical values, i.e., representative soil properties as compiled from soil survey reports and historical daily weather data (precipitation and temperature) from Environment Canada. The Agency will add new scenarios and update existing ones on an ongoing basis to ensure that the scenarios remain current with respect to agricultural practices and weather patterns in Canada. New scenarios will undergo a thorough scientific review prior to being adopted.

3.2 Surface water

3.2.1 Choice of surface water model

The PMRA estimates surface water concentrations at all levels of its drinking water assessment using the linked PRZM and EXAMS models. These models were developed by the USEPA and have been used for several years in North America and Europe. The USEPA uses PRZM-EXAMS in their Tier 2 assessment. These models account for the various factors affecting the surface runoff from the field, and the transformation and partitioning occurring in the water body. They are used to estimate EECs for both reservoirs and dugouts using Canadian soil, crop and weather information.

The PRZM model is used to predict the pesticide concentration dissolved in runoff waters and carried on entrained soil particles that will move from the field where the pesticide has been applied into an adjacent surface water body. Input parameters include the characteristics of the pesticide (physico-chemical properties, transformation half-lives and mobility data), pesticide use information (application rate, frequency and timing), crop growth information, site specific information (soil properties, local topography, hydrologic conditions and agricultural practices) and weather data. In the United States, the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) Environmental Model Validation Task Force concluded that PRZM simulations conducted using realistic input parameters generated results within an order of magnitude of the measured data (Jones and Russell, 2001).

The EXAMS model is used to simulate environmental fate and transport processes of a pesticide once it enters a body of water. Such processes include volatilization, sorption, hydrolysis, biotransformation and photolysis of the pesticide. Inputs include parameters defining these processes, limnological and physical characteristics of the water body, and weather data.

In a Level 1 surface water assessment, multi-year PRZM-EXAMS simulations are conducted for the agricultural scenarios with appropriate water bodies (sections 3.1 and 3.2.2). From these simulations, the scenarios (for reservoir and dugout) producing the highest concentration are selected. While the scenarios represent typical soil, weather, plant growth and cultivation related information, a Level 1 assessment uses conservative values of the pesticide's fate characteristics (where multiple values exist) and application information. A pesticide specific approach is taken for the Level 2 surface water assessment, where the Agency may undertake any or all of the following: use input parameters that more accurately reflect the use pattern of the chemical in question; restrict the modelling to scenarios that reflect the current or proposed uses of the pesticide; use valid monitoring and percent cropped area information; and, request additional studies.

PRZM-EXAMS simulations can generate output in a variety of formats. The PMRA uses the one-in-ten year (90th percentile) value of the yearly maxima of daily concentrations and the 90th percentile value of the average yearly concentration to represent the acute and chronic exposures, respectively.

3.2.2 Choice of receiving water body

Surface drinking water sources include natural water bodies like rivers and lakes, as well as constructed water bodies like reservoirs and dugouts (Reedyk et al., 2000; Prairie Water News, 2002; Jones et al., 1998). The choice of a receiving water body for use with surface water models should be representative of surface drinking water sources that are considered to be vulnerable to pesticide contamination in Canada. Small water bodies in areas with a high run-off potential and a high pesticide use rate are considered to be more vulnerable than a large water body in an area that does not favour run-off and has low pesticide use.

In estimating pesticide concentrations due to runoff in surface drinking water sources, two hydrometric scenarios are currently used: (1) a reservoir scenario, representative of a water supply in smaller municipalities; and (2) a farm dugout scenario representing the dugouts used in the Canadian prairies. These two hydrometric scenarios are considered to be particularly vulnerable because of their potential for contamination from local agricultural practices. Other scenarios may be added in the future, but for the present, modelling is limited to these two scenarios.

In 1998, the USEPA compiled a list of 82 candidate reservoirs and selected the Shipman reservoir in Illinois as their index drinking water reservoir for modelling. The Shipman reservoir is representative of reservoirs in the central mid-western U.S. that are vulnerable to pesticide contamination, and it has appropriate pesticide monitoring data (USEPA, 1999). A USEPA monitoring program[5] ranked the Shipman reservoir 8th out of 175 surface water sites in terms of atrazine concentrations, indicating that it represents a vulnerable surface water reservoir. Following the U.S. rationale, the PMRA undertook a review of the Municipal (Water) Use Database (MUD) to identify municipal water sources that were located in some of the major agricultural areas in Canada (Ontario, Manitoba, Saskatchewan and Alberta; Environment Canada, 1999). Water sources were evaluated using the following criteria:

(1)   The capacity or volume of the water body had to be small enough that it could be effectively modelled with PRZM-EXAMS; and

(2)   The reservoir or lake had to be located within a drainage system where agriculture was prevalent.

In addition, a water body with a monitoring program and a history of pesticide detections was sought. Although there were several water bodies in Canada that were of the requisite size and located in intensive agricultural areas, none of these had an adequate monitoring program. As the Shipman reservoir has all the required physical information to be useful in the model, the PMRA has adopted the dimensions of the Shipman reservoir (surface area and drainage area) for use with PRZM–EXAMS. This is considered to be an interim solution until a more representative Canadian reservoir can be found. The Shipman reservoir is acceptable for use because, apart from the reservoir dimensions and watershed area, other site-specific information such as weather, soil, crop and hydrological data are Canadian in origin and are representative of the Canadian area being modelled and not of Shipman, Illinois.

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[5]   These sites included reservoirs, lakes and flowing water (USEPA, 1999)

The PMRA has developed a prairie dugout scenario to be used, in addition to the reservoir scenario, when estimating drinking water concentrations of pesticides that are used in the prairie provinces. The Agency considered prairie dugouts as a second vulnerable surface drinking water source in Canada, as they are used as a household water supply, including for drinking, and they tend to be in close proximity to pesticide-treated fields (Prairie Water News, 2002).

Rivers and streams also constitute potential drinking water sources that may be vulnerable to pesticide runoff. The PMRA is not, however, planning to develop separate scenarios for rivers or streams as sources of drinking water because the index reservoir is considered a high exposure scenario for surface water in general.

3.3   Groundwater

3.3.1   Choice of groundwater model

The PMRA evaluated five computer models that simulate leaching through soil, for use in estimating EECs in groundwater. The models evaluated were MACRO, LEACHM, SCI-GROW (Screening Concentration in Groundwater), PESTAN (Pesticide Transport Model) and PRZM/VADOFT (Vardose Zone Flow and Transport Model). There were four primary requirements for a soil leaching model:

- •   the model's source code had to be available and modifiable;
- •   the model had to be able to evaluate a range of different environmental conditions (i.e., climate and soil);
- •   the model's input requirements had to be similar to the data already being submitted to the Agency; and
- •   the model had to be user-friendly.

Of the models considered, only LEACHM was found to meet all four requirements; consequently, the PMRA decided to use LEACHM to model leaching to groundwater, for all levels of its drinking water assessments.

LEACHM is a suite of models that simulate the movement and fate of water and chemicals within a soil profile (Hutson, 2003). The development of LEACHM has occurred gradually over the last several decades, with periodic updates and revisions based on testing, evaluation and feedback from soil scientists around the world. The current version of the model, its source code and a user's guide are available to the public (http://www.scieng.flinders.edu.au/cpes/people/hutson_j/leachweb.html).

Numerous researchers have evaluated LEACHM's performance against experimental data and field data from various countries. In Canada, laboratory and field studies have been used to test and calibrate LEACHM (Reynolds et al., 1994; de Jong et al., 1994; Smith et al., 1995). Overall, LEACHM was found to provide excellent predictions of water content and hydraulic head profiles, and adequate to good predictions of chemical

transport behaviour. The model predictions were also found to compare favourably with the results of a groundwater quality survey in southern Ontario (Agriculture Canada, 1992). The PMRA also undertook an internal assessment of LEACHM's ability to simulate the fate and transport of several different pesticides and a tracer. In the model tests, the simulated pesticide concentrations were compared to a detailed field study of pesticide fate and transport at a site in the Netherlands (Boesten and van der Pas, 1999). This comprehensive data set has been used by various researchers (Vanclooster and Boesten, 2000; Tiktak, 2000). The results from the Canadian studies and the internal assessment indicated that LEACHM performed well in predicting both the movement and quantity of pesticide in the soil profile.

As with PRZM–EXAMS, input parameters for the pesticide version of LEACHM include pesticide-specific physico-chemical properties, fate characteristics, site-specific soil properties and weather data (rainfall and temperature), pesticide application information and (optionally) crop-specific data. The model simulates water and pesticide movement in soil over one or more growing seasons.

3.3.2   Approach for calculating EECs in groundwater

The PMRA estimates EECs in groundwater that is considered to be vulnerable to pesticide contamination. As a result of pesticide leaching through soil, shallow groundwater will usually contain higher concentrations of pesticides than deeper groundwater, where the residence time has been longer and there has been more opportunity for pesticide concentrations to attenuate by physical, chemical and biological processes including dilution, dispersion and degradation. Groundwater used for drinking water is drawn from both shallow and deeper depths (Ontario Ministry of the Environment, 2000; Rudolph and Goss, 1993; Agriculture Canada, 1992; Fleming, 1992). Pesticide concentrations estimated in shallow groundwater are considered protective of all potential groundwater drinking sources.

In a Level 1 groundwater assessment, multi-year LEACHM simulations are conducted for the scenarios described in Section 3.1, which represent different geographic regions of significant agricultural activity in Canada. From this, the scenario producing the highest concentration is selected. While the scenarios represent typical soil and climatic conditions in each agricultural region, a Level 1 assessment uses conservative values of the pesticide's fate characteristics (where multiple values exist) and maximum rates of application. As with surface water, a pesticide specific approach is taken for the Level 2 groundwater assessment. In a Level 2 groundwater assessment, the Agency may undertake any or all of the following: use input parameters that more accurately reflect the use pattern of the chemical in question; restrict the modelling to scenarios that reflect the current or proposed uses of the pesticide; consider monitoring data; and, request additional studies.

Output from the LEACHM model includes the distribution of pesticide concentrations in the soil profile and the flux of water and pesticide across a specified boundary, such as the water table. These results are used to estimate EECs in groundwater.

The PMRA considered two approaches to calculating EECs in groundwater. They are referred to as the depth-averaged approach and the flux-averaged approach, both of which are used in European regulatory contexts. Both approaches are based on the assumption that the groundwater present near the top of the water table is potentially vulnerable to contamination from non-point sources (such as pesticides).

The depth-averaging approach, which is used in the Dutch registration process (Tiktak et al., 2000), averages the concentration of the pesticide of interest in the top one metre below the water table. This method produces a depth-averaged concentration, which is the average of the concentrations, in a number of adjacent soil layers. The flux-averaging approach estimates the flux-averaged concentration by taking the mass flux of pesticide across a boundary during a certain time period, divided by the volume flux of water across that boundary during the same time period. This second approach is recommended by the Forum for the Co-ordination of Pesticide Fate Models and Their Use (FOCUS) for use in the EU pesticide registration process. The FOCUS group has recommended that all models used in the EU registration process should report flux averaged concentrations at a depth of one metre for comparative purposes (FOCUS, 2002). Both approaches estimate pesticide concentrations in shallow groundwater and, presumably, vulnerable groundwater drinking sources.

The PMRA has evaluated the depth-averaged versus the flux-averaged approach to compute groundwater concentrations using the results of LEACHM simulations. The evaluation indicated that the two approaches produce similar results for the typical scenarios simulated. Conceptually, the flux-averaged approach is preferable as it preserves mass balance (by accounting for all the pesticide mass that crosses the water table) while the depth-averaging concentration does not. In addition, the flux-averaged approach offers computational advantages in terms of smaller output file sizes. The PMRA selected the flux-averaged approach as the preferred method, based on conceptual grounds and computational practicalities.

3.4   The use of monitoring data

In the drinking water assessment of registered products, the Agency makes use of available monitoring data pertinent to the pesticide under review. Valid monitoring data would be considered preferable to estimates generated using water models; however, for new chemicals, monitoring data will be unavailable. In such cases, where monitoring data would be essential for conducting a refined exposure assessment, registrants would be requested to conduct field studies. The majority of available monitoring studies and data are likely to be for pesticide products that have been on the market for some time. These monitoring studies are expected to vary considerably as to the quality and quantity of available data and with the amount of contextual information described below.

In evaluating, characterizing and interpreting water monitoring data, the PMRA attempts to collect as much information as is readily available on the design of the studies. This includes information on how the samples were collected and analysed, why they were collected, and where and when they were collected. In evaluating the quality of monitoring data, the Agency considers the spatial and temporal conditions under which the monitoring was conducted. Spatial considerations include whether the data originate from areas of pesticide use and temporal considerations include information relating the timing of pesticide application to the timing of sampling. Other important ancillary data include accurate weather data, hydrological data (size and type of receiving water body, depth of groundwater), and geochemical and geophysical characteristics (topography, soil characterization).

The level of variability and uncertainty associated with existing monitoring data in Canada means that the use of these data to predict EECs can be challenging. Reported concentrations may vary considerably over time at the same location and from one area to the next. Without having specific information on the history of use of the pesticide in the sampled area, it is very difficult to fully understand the reasons for these differences. Further, the PMRA is not always able to discern whether samples were taken from potential drinking water sources or waters that would be representative of such drinking water sources. The frequency with which samples are taken in monitoring studies is often insufficient to allow a determination of peak concentrations. Peak concentrations, by nature, occur over short times, and sampling frequencies in many studies are quarterly or monthly, giving a low probability of sampling during the period of peak concentration.

Interpreting the results of studies that include a large number of samples with no residues (i.e., "non-detects") poses additional difficulties. Non-detects can indicate that the pesticide of concern is not reaching the drinking water source. However, non-detects can also result when the samples are taken from areas where the pesticide is not applied or at times when the pesticide is not being used or in the case of leaching to groundwater, samples may be taken from groundwater before "breakthrough" to the water table occurred. Limitations of analytical methods may also result in non-detects (i.e., the pesticide may be present in the water at concentrations that are less than the limit of detection for the analytical method or the analytical method may not be appropriate for certain compounds).

For these reasons, the PMRA considers such factors in interpreting non-detects in monitoring data sets. The Agency often lacks data to verify that reported "non-detects" were in actual areas of pesticide use and therefore has difficulty concluding that the pesticide, when used, is not in fact reaching water frequently enough to be of concern. As a result, the PMRA will assign a value equivalent to half the limit of detection (LOD) to non-detects in datasets where it is deemed appropriate. This may occur when (1) non-detects in a dataset that contains at least one detection or (2) a dataset where there are no detections but it is determined that the particular active ingredient may be used within the watershed sampled and that there is a potential for the active ingredient to contaminate water bodies. This approach has been used by the USEPA during their re-evaluation of

several pesticides, including diazinon and triallate (http://www.epa.gov/pesticides/op/diazinon/water.pdf and http://www.epa.gov/oppsrrd1/reregistration/triallate/triallate.efed.red.pdf), and is protective of drinking water sources that may be receiving pesticide residues in quantities too small to be measured.

Despite the challenge of analysing and interpreting these data, the PMRA will use the results of monitoring data, when valid data are available, to make decisions with respect to the expected concentration of a pesticide in drinking water. Monitoring data that are limited with respect to temporal and spatial information are always considered as part of the overall risk assessment, but the weight given to these data will vary depending on the circumstances. For instance, if monitoring data of marginal quality consistently yield estimated concentrations that are higher than those predicted by the exposure models, then the weight given to the monitoring data would be higher than if the monitoring data yielded a series of non-detections.

Overall there is a paucity of pesticide drinking water monitoring data in Canada that have adequate temporal and spatial ancillary data. The PMRA's risk assessments would be strengthened if future monitoring programs were to include these ancillary data. The Agency is working on a number of levels to fill in these gaps and acquire more high-quality data on pesticide concentrations in drinking water sources. Cooperation with other jurisdictions within the federal, provincial, territorial and municipal levels of government will be important in this process.

3.5   Factoring in water treatment

The degree to which drinking water is treated prior to consumption varies greatly in Canada. Owners of private wells often consume untreated water. Many municipalities employ at least a basic system of coagulation, filtration and disinfection, or may have additional treatment steps such as activated carbon adsorption. In addition, Canadians may further treat their drinking water using commercially available water purification systems designed for household use. It is known that different treatment systems remove certain classes of pesticides more effectively than others (USEPA, 2001; Miltner et al., 1989; Baier et al., 1987; Clark et al., 1988). Due to the wide variety in the degree of water treatment as well as the differences in the degree of removal of pesticides by the differing treatment technologies, the PMRA has opted not to factor in pesticide removal by water treatment in its drinking water assessment. Therefore, estimated pesticide concentrations generated for use in dietary risk assessments will not routinely reflect the effects of water treatment.

4.0   How EECs are incorporated into a risk assessment

Once estimates of pesticide concentrations in drinking water have been generated by the Agency, they are compared with the DWLOC. If the EECs are less than the DWLOC, the PMRA concludes with reasonable certainty that residues of the pesticide in drinking water from present uses are below a risk level of concern. Alternatively, the EECs may be incorporated directly into the dietary risk assessment. It should, however, be noted that either approach, DWLOC or the direct incorporation of the EEC, does not result in differences in the risk assessment. Details of these processes can be obtained in PMRA Science Policy Notice SPN2003-04, *General Principles for Performing Aggregate Exposure and Risk Assessments* (PMRA, 2003).

5.0   Future directions

The process of estimating pesticide concentrations in Canadian drinking water sources is evolving. The Agency is formalising procedures for the Level 1 and Level 2 assessments of both new pesticides and those undergoing re-evaluation. In order to improve the process of estimating pesticide concentrations in drinking water, the Agency will continue:

• To conduct sensitivity analyses on the surface water and groundwater models to identify the factors that are most important in influencing EECs in drinking water sources. The information obtained from sensitivity analyses will aid in the development of modelling techniques for Level 2 assessment.

• To update the current agricultural scenarios and create new scenarios as needed.

• To search for a representative Canadian reservoir to use with the surface water models.

• To actively pursue opportunities to develop high-quality national scale valid monitoring data with the provinces, territories and municipalities, as well as other federal departments.

• To evaluate the effect of water treatment on the formation of toxic metabolites. Water treatment has the potential to create toxic breakdown products that may persist in treated drinking water (e.g., chlorination of organophosphate compounds can lead to oxon formation, which can be significantly more toxic than the parent compound. It is currently unknown to what extend oxon formation occurs [USEPA, 2001]) and to what degree these compounds persist after their formation. Given these concerns, the PMRA will examine the effect of water treatment on the formation of toxic metabolites.

- To pursue the development of probabilistic techniques for risk assessment, as the Agency's approach is evolving from a deterministic approach to a probabilistic one. The PMRA will consider modifying models or adopting new models that generate outputs for probabilistic risk assessments, as well as examine whether the outputs from the current water models can be adapted for use in a probabilistic assessment of pesticide exposure.

- To monitor and evaluate new and evolving approaches in other jurisdictions, such as the U.S. and the EU. The PMRA's surface water modelling is similar to that of the USEPA's Tier 2 approach. The Agency will, however, evaluate the modelling developments, if any, occurring in other jurisdictions.

List of abbreviations

DWLOC drinking water level of comparison
EU European Union
EEC expected environmental concentration
EXAMS Exposure Analysis Modelling System
EXPRES Expert System for Pesticide Regulatory Evaluation Simulations
FIFRA *Federal Insecticide, Fungicide, and Rodenticide Act*
FOCUS Forum for the Co-ordination of Pesticide Fate Models and Their Use
LEACHM Leaching Estimation and Chemistry Model
K_d soil–water partition coefficient
K_{oc} organic carbon adsorption coefficient
LOD limit of detection
MUD Municipal (Water) Use Database
PESTAN Pesticide Transport Model
PRZM Pesticide Root Zone Model
PMRA Pest Management Regulatory Agency
SCI-GROW Screening Concentration in Groundwater
U.S. United States
USEPA United States Environmental Protection Agency
VADOFT Vardose Zone Flow and Transport Model

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