

1.0 Introduction

Background

The Food Quality Protection Act (FQPA) of 1996 significantly amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). One of the major changes is the requirement that EPA consider risk posed by pesticides acting by common mechanism of toxicity. For such groups of pesticides, EPA's Office of Pesticide Programs (OPP) has defined cumulative risk as the risk of a common toxic effect associated with concurrent exposure by all relevant pathways and routes.

Since the enactment of FQPA, OPP has been working to develop new methodologies in a number of risk assessment areas. One such area is the development of assessments using multiple models of cumulative risk. This report was prepared for OPP by The LifeLine Group. The report presents an assessment of the cumulative risks presented to the general US population and selected subpopulations from exposures to organophosphorus (OP) pesticides. The uses of OP pesticides included in this analysis were provided to The LifeLine Group by OPP. Decisions to include, or not include, specific pesticides, uses of the pesticide, or residues from an OP on foods were made by EPA.

This assessment is performed with LifeLine™ Version 2.0. LifeLine software was developed by The LifeLine Group a nonprofit 501(c) (3) corporation with funding from EPA, Health Canada, and Bayer Crop Life. LifeLine software was reviewed by the EPA Science Advisory Panel on three occasions; September 22, 1999, September 26, 2000, and March 28, 2001. In the final report of the March 28, 2001 meeting, the SAP recommended LifeLine™ software as a "very useful" tool for the assessment of aggregate and cumulative risks. LifeLine software has also been used in the assessment of dietary exposures for pesticides (Fed Reg. 4/17/02, p. 18893). EPA reported the results of the dietary portion of the cumulative assessment of OP pesticides performed using LifeLine Version 2.0 at the June 2002 SAP meeting.

LifeLine™ Version 2.0 is an advanced software program that determines the cumulative exposures to pesticides from dietary, tapwater and residential exposure. Exposures are determined on a national basis using regional data on crop use patterns and how they may affect tapwater residues. In addition, region and season specific data on residential pesticide uses are used to predict the geographic co-occurrence of residential and tapwater exposures. Finally, seasonal variation in both dietary and non-dietary exposures are considered. LifeLine's assessments of exposure and risk are consistent on a demographic, temporal, and chronological basis. Additional information on the LifeLine software is available in the User and Technical Manuals provided with the software.

LifeLine™ Version 2.0 is available without charge. A copy of the form for ordering the software is attached to this report as Appendix A.

Purpose of this Assessment

At the June 26, 2002 Science Advisory Panel meeting, EPA presented a comparison of the dietary risks for OP pesticides calculated with LifeLine™ Version 2.0 and with a trade-secret program licensed by EPA, Calendex™. This report is an expansion of that analysis of OP cumulative risks using LifeLine™ Version 2.0.

The purpose of this assessment is twofold. First, the assessments previously presented by EPA were calculated using a software program, Calendex™. The agency made the input files for the risk assessment publicly available; however, to use these files requires access to the Calendex™ software. Because of Calendex's limited availability and high cost, the public could not independently examine the assessment. In addition, the code for Calendex™ software is a trade secret and is not available for independent verification. Second, EPA recognizes that the design of any model influences the model's predictions of exposure and risk to some degree (modeling uncertainty). One approach for evaluating model uncertainty is to apply the same data to

independently developed models and compare the resulting assessments. This will provide EPA with perspective on whether the agency's findings are model dependent.

The assessment presented in this report addresses both the issues of availability and transparency of models and the need for perspective on model uncertainty. As discussed above, LifeLine™ Version 2.0 is available without charge to any interested party¹. A copy of this report and the input files for the analyses performed in this assessment are posted on EPA's web page. These files and LifeLine Version 2.0 will allow all interested parties the opportunity to replicate and expand the results presented in this report. The design and coding for LifeLine™ Version 2.0 are fundamentally different from that used by Calendex™ and thus provide an independent assessment of OP cumulative risks. The details of the design of LifeLine™ are presented in the technical documentation provided with the software.

Approach

The data describing OP use and residues on food, water and residential environments were provided to The LifeLine Group by EPA for this assessment. The objective was to apply the same data applied to the Calendex™ model, as provided and directed by EPA. The resulting assessment would include risk estimates that were comparable to the estimates provided by Calendex™, plus additional risk characterizations possible with the assessment features in LifeLine™. These additional risk characterizations provide expanded insights into OP cumulative risks.

As discussed in Chapters 2.0 and 6.0, the dose response information and the risk characterization approaches in this report are those provided to The LifeLine Group by EPA, and are the same as those used by EPA in the prior OP assessment. EPA provided all residue data for the tapwater, dietary, and residential assessments. In certain instances, assumptions for the residential

¹A copy of the complete code for LifeLine Version 2.0 is available for the purpose of verifying how the program functions and its consistency with its guidance documents.

exposure were adapted to the design of LifeLine™. A detailed description of the data used, and how it was entered for the dietary, tapwater and residential exposure assessments are presented in Chapters 3.0, 4.0 and 5.0.

LifeLine™ Version 2.0 can characterize exposure and risk in ways not previously possible. The comparisons of dietary risk presented by EPA at the June 26, 2002 Science Advisory Panel were only one of the risk characterizations possible with LifeLine™. This one characterization closely matches the Calendex™ output. EPA correctly made the point that these models can give similar answers for the OP Cumulative Risk Assessment (dietary) where the comparisons between models are possible². Chapter 6.0 presents the discussion of the array of risk characterizations options provide by LifeLine™ Version 2.0.

Chapter 7.0 presents the results of the cumulative assessment as extracted, and organized by The LifeLine Group. Cumulative Risk Assessment is a complex analysis and the results in this report are not a collection of numbers or bright lines that in isolation determine risk findings. Quantitative methods have been used throughout the analysis but the results need to be interpreted with a full understanding of the assumptions made and the uncertainties introduced by making these assumptions. Such evaluations are beyond the scope of this report.

²One should not conclude from this comparison, however, that the models operate identically, nor assume other analyses with a different arrays of pesticide uses would always yield similar answers. The present similarity may be due, in part, to the vast number of uses considered in this OP assessment. Differences in calculations for any particular uses could be hidden by other pesticides or could be averaged out by the large number of uses and pesticides involved in the assessment.