Comments Before the Scientific Advisory Panel – "Cumulative Risk: A Case Study of the Estimation of Risk From 24 Organophosphate Pesticides"

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Submitted By:
Consumers Union
National Campaign for Pesticide Policy Reform
Farmworker Justice Fund
Environmental Working Group
Natural Resources Defense Council

These comments are submitted on behalf of Consumers Union of United States, Inc.,[1] the National Campaign for Pesticide Policy Reform,[2] Farmworker Justice Fund, Inc.,[3] Environmental Working Group,[4] and Natural Resources Defense Council.[5] A year ago, on

[1] Consumers Union (CU) is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finances and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

[2] The National Campaign for Pesticide Policy Reform (NCPPR) was formed in December, 1993. The goal of the campaign is to press for new pesticide policy reforms that better protect children from pesticide exposures and reduce the use of harmful pesticides.

[3] The Farmworker Justice Fund, Inc. (FJF) is a nonprofit, national advocacy organization which is dedicated to improving the living and working conditions of migrant and seasonal farmworkers and their families. For two decades, FJF has advocated for the reduction and/or elimination of the use of toxic pesticides.

[4] The Environmental Working Group (EWG) is a non-profit environmental research organization with offices in Washington DC, Oakland, and Seattle.

[5] The Natural Resources Defense Council (NRDC) is a national, non-profit environmental membership organization with over 400,000 members and contributors nationwide. Many NRDC members, including pregnant women and children, are exposed to pesticides in their diet and through other sources, thereby creating risks to human health. NRDC has no financial or fiduciary interest, either direct or indirect, in entities that manufacture, sell, or use pesticide chemicals.

December 9, we appeared before the SAP to present comments[6] on the new risk assessment and regulatory policies embedded in Chapters 4 and 6 of the EPA document "Proposed Guidance on Cumulative Risk Assessment (CRA) of Pesticidal Chemicals That Have a Common Mechanism of Toxicity." On September 15, 2000, we submitted detailed comments to EPA on its revised CRA science policy.[7] Our September comments address many critical technical issues that the agency still must struggle with as it refines its CRA methodology. Our comments today, though, focus on broader and more fundamental issues that arise in estimating cumulative organophosphate (OP) dietary exposure and risks.

We commend the agency for steady progress in the past year in refining and explaining its CRA methodology. The agency has brought science policy issues central to cumulative risk assessment before the Scientific Advisory Panel (SAP) seven times since the initial presentation on March 19, 1997. This meeting is number eight. We doubt it will be the last.

With each new draft of its CRA policy, the agency has incorporated the advice of the SAP and responded to the suggestions, criticisms and concerns raised by people and organizations that have submitted comments during SAP sessions or to the public docket. We regret that timely completion of the much-needed CRA on the organophosphates has fallen victim to process, but remain hopeful that the integrity of the final CRA science policy and the methodologies within it, will serve the program well for many years.

From our review of EPA's work to date on the cumulative risk assessment for the OPs, we have the following observations and recommendations, which are dealt with in greater detail below:

1. EPA must utilize a full 10-fold safety factor with the cumulative risk assessment for the OPs;
2. the dietary assessment should present in detail, and empirically, the contribution of different pesticide-food combinations to overall risk;
3. the final OP cumulative risk assessment should include the carbamates found in food;
4. Pesticide Data Program data should remain the backbone of OP-carbamate cumulative risk assessments;
5. the Pesticide Data Program must be expanded and improved to reduce exposure data uncertainty; and
6. use of composite Pesticide Date Program data underestimates high-end exposures, and metabolites and isomers must be included in the OP cumulative risk assessment.

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[6] The December 9, 1999, comments, delivered on behalf of CU and NRDC, are accessible at <http://www.ecologic-ipm.com/cumulative_risk.pdf>.

[7] The September 15, 2000, comments were submitted on behalf of CU, FJF, and NCPPR. They are accessible at <http://www.ecologic-ipm.com/CRA_sept00.pdf>.

A. The OP Cumulative Risk Assessment is a Major Milestone and Marker

Completion of this first preliminary cumulative risk assessment of the organophosphate insecticides (OP-CRA) is a major step and culminates an enormous amount of work. But as evident in the questions posed to the SAP, important issues remain to be settled so that the agency can issue its final CRA of the OPs.

We strongly urge EPA to at least preliminarily settle the remaining issues, such as the appropriate selection of endpoints and bridging data across toxicological studies and residue data, so that the Office of Pesticide Programs can complete the CRA of the OPs within the next several weeks. With a Presidential transition ahead, there will be a period of time, perhaps spanning close to a year, when few important policy decisions or technical findings and documents will be released. This could lead to a long delay in the completion of an initial CRA of the OPs. Such a delay will trigger unnecessary and unwarranted anxiety in the farm community and further set back attainment of the Food Quality Protection Act (FQPA)'s basic goals.

EPA should complete its cumulative assessment of the OPs and officially release the results prior to the transition. The results should include, of course, chemical names and not just numbers. EPA must also incorporate in the final OP-CRA the FQPA safety factor which the agency deems appropriate given the unequivocal evidence that exposures to pesticides in this family of chemistry pose heightened risk to infants and children.

As the agency well knows, the FQPA requires the use of an additional safety factor where special sensitivities or uncertainties exist with regard to target populations or data. While we recognize the need for the use of common endpoints or reference points in the development of cumulative risk assessments, we believe that this necessity creates additional uncertainties in the use of the data and requires the maximum protection – the full ten-fold safety factor. Major uncertainty is created precisely because the common endpoint and not the most sensitive endpoint is used. In the case of the OPs, an additional safety factor is required for about two-thirds of the pesticides assessed. The risk assessments of the major risk drivers, such as chlorpyrifos, incorporated the full 10-X safety factor. Therefore, in order to ensure a properly conservative approach, 10-X must be used in the cumulative assessment for the OPs.

We offer further justification for a full 10-X safety factor in highlighting uncertainties in dietary exposure assessments later in these comments.

Under any circumstances, EPA should not pass this buck to the next Administration. The current team of scientists and policy-makers has carried to fruition the process of assigning

FQPA safety factors to all individual OPs, for both chronic and acute exposures, often with carefully tailored, restricted added safety factors for certain populations or routes of exposure. One last major decision must be made. It is far more likely that the decision will be defensible and consistent with the past review of OP toxicological data if made by the current team, applying the criteria they have developed and applied to all individual OPs, along with their in-depth knowledge of OP toxicological data.

The dietary assessment should present in detail, and empirically, the contribution of different pesticide-food combinations to overall risk, as well as each pesticide's contribution summed across foods, and each food's contribution aggregated across OPs with residues appearing in food tested by the United States Department of Agriculture (USDA)'s Pesticide Data Program (PDP).

We suggested in our comments before the SAP last year a straightforward way to attain insights on the contributions to and distribution of OP dietary risks. The basic approach is to disaggregate exposure and risk in all eating day episodes that exceed a given high point in the distribution of exposures – say the 99th percentile of exposure. Total exposures in a day would be disaggregated according to each pesticide-food combination that plays a role in the eating days. Analysis of the contribution of each pesticide-food combination to these high-end exposures is the most rigorous, data-rich way to monitor attainment of risk reduction goals and to identify priorities for future risk mitigation, if and when needed to meet the FQPA's "reasonable certainty of no harm" standard.

The final OP-CRA that we hope EPA will soon release should include PDP data through crop year 1999, as the present case study does. Accordingly, it will reflect pesticide use patterns and residues prior to any significant EPA food use actions on the OPs. The agency should run this initial CRA two ways – one reflecting tolerances on the books and pesticide use in 1999. This will be, in effect, a pre-FQPA implementation baseline. The agency should run a second, related CRA, much like the case study under review today, incorporating the risk reduction actions imposed on methyl parathion and chlorpyrifos, and any other actions taken to date with a realistic prospect of reducing dietary exposure. The results of this second CRA, in contrast to the first, will provide an estimate of the risk reduction embedded in actions taken to date.

Annually, as new PDP data become available, the agency should update the residue database and rerun the CRA in order to determine whether projected – and hoped for – risk reduction has in fact been achieved. This is the only realistic way to monitor attainment of risk reduction targets and to determine if further, or fewer risk mitigation measures are needed. Moreover, with each year of new data, the accuracy and reliability of CRA results are bound to improve. In time the results will lead to invaluable insights into pest management research and development priorities and areas where the industry should invest in new chemistry and biopesticides.

B. Expanding the Scope and Accuracy of Future OP Cumulative Risk Assessments

The Final OP-CRA Should Include the Carbamates Found in Food

Given the clear guidance from the SAP as a result of earlier reviews of the OP-carbamate common mechanism group, we wonder why this case study includes only the 24 OPs commonly found in food. The SAP, along with all other scientific bodies reviewing the issue for EPA, has stated clearly that the OP cumulative assessment should include the carbamate insecticides. Given the prominence of residues of some carbamates in foods tested by PDP, it is critical for EPA to expand the scope of its final OP-CRA to encompass the carbamates.

Based on CU's assessment of 1994-1999 PDP data, this will add at least four aldicarb, 22 carbaryl, eight carbofuran, 15 methomyl, and nine oxamyl pesticide-food combinations to the CRA, for a total of 58 pesticide-food combinations. By contrast there are just over 180 OP-food combinations with a positive residue in 1994-1999 PDP testing.

PDP Data Should Remain the Backbone of OP-Carbamate CRAs

In the questions posed to the SAP, the agency seeks guidance on a number of technical issues regarding whether and how to estimate exposures in the absence of solid monitoring data, such as the data from the PDP. On the dietary side, we remain convinced that the PDP program is well focused on the major fresh fruit and vegetable crops accounting for most OP exposure and risk. We support the agency's decision to focus its OP-CRA on those OPs appearing in foods tested by the PDP. The results point to unequivocal risk drivers, which the agency has started to address through risk mitigation measures. Much remains to be done, however, as documented in our comments on further steps needed to mitigate excessive chlorpyrifos dietary risks.[8]

Expand and Improve the PDP to Reduce Exposure Data Uncertainty

In light of the agency's decision to regulate the OPs and carbamates based on acute dietary exposures, it is critical to work with USDA in expanding and refining the PDP to include additional fruits and vegetables which are often eaten in substantial quantities by children, especially when in season and readily accessible in stores and from produce stands. Such crops and foods are sometimes heavily treated with OPs – cherries, berries, watermelons, green peppers, cucumbers, and cherry tomatoes are examples. We have also recommended to USDA that it expand the number of imported food samples tested, especially for critical foods like apple juice, which is beginning to move in substantial quantities in international commerce.

[8] CU's comments to the public docket on additional steps needed to mitigate chlorpyrifos dietary risks are accessible at <http://www.ecologic-ipm.com/Chlorpyrifos_comments_2000.pdf>.

The nation's supply of most fresh fruits and vegetables is grown and packaged in relatively few areas. Distinct geographic areas account for the largest share of the supply at different times of the year; USDA pesticide use data is reported by crop and state, allowing the PDP program to target the regions where high-risk pesticides are relied on most heavily. As a result, we suspect that useful and reliable results can be obtained with far fewer than the typical 625 samples the PDP now analyzes annually for most foods in the program.

Even 100 to 200 samples would provide adequate data to determine whether more in depth sampling is warranted. If a portion of PDP resources each year – say one-third – were committed to such screening level studies, perhaps six to eight new foods could be analyzed each year. This approach would soon dramatically expand the coverage of the program and the confidence that can be placed in the results of future PDP-based CRAs of the OPs.

In the interim, we support EPA's efforts to use bridging methods and data surrogation to develop PDP-like datasets for additional crops related to crops with PDP data. While we doubt that many such crops will emerge as risk-drivers, it is still important for EPA to include them in OP-CRAs. After all, there are some 600 food uses of OPs. We concur with EPA's caveat that it will only strive to bridge data between similar crops treated with similar use patterns.

We also think the agency should make fuller use of the important new 10-X authority in the FQPA to address exposure data gaps. We strongly urge EPA to incorporate at least an additional 3-X safety factor in the OP-CRA to account for gaps in exposure data. This is in addition to the 10-X factor that should be added because of heightened pre- and postnatal sensitivities. The statute clearly calls for such use of the 10-X provision. And doing so may help broaden the coalition willing to support appropriation of additional resources for the PDP, an investment that will pay major dividends over the next several years as FQPA implementation moves ahead.

Use of Composite Data Underestimates High-End Exposures

We understand why EPA chose in this case study to use composite PDP data. Clearly, this decision substantially underestimates high-end exposures. Somehow the agency must factor this into future CRA results. Two obvious solutions exist. The agency could include an additional 3-X exposure-uncertainty factor in judging the acceptability of the estimated CRA risk. This is, of course, in addition to the overall 10-X safety factor justified for reasons outlined above.

The second option, of course, is to forge ahead in the ongoing effort to reach agreement on a practical method to decomposite PDP results. This strategy, even if successful, entails time and costs in implementation. As in many other aspects of CRA and FQPA implementation, EPA needs to balance the need for expediency and decisiveness in decision-making, essential

ingredients in achieving public health gains, against refinements in risk assessment science and accuracy.

Metabolites and Isomers Must Be Included In OP-CRAs

The agency's case study does not explain how the current OP-CRA deals with cases where the PDP reports residues in the same food of a parent compound and one or more metabolite and/or isomer. This is a tricky and important issue. We infer from the tables in this case study that EPA included just parent-compound residues. In many cases though, PDP reports data on well-known breakdown products in the same food, i.e. dimethoate and omethoate. Often, both the parent compound and metabolite are found in roughly the same percent of samples, although the mean residue levels tend to differ significantly.

In future CRAs, we urge EPA to include all residues found by PDP in cases where a parent compound and distinct metabolites and/or isomers are found in the same food. After all, both residues are present in the food and are ingested and in most cases contribute to OP risk. In recent years, the PDP has started reporting different isomers for some pesticides like permethrin, along with an estimate of "Total Permethrin." In such cases, the agency should just use the estimate of total residues. To the extent this approach simplifies future CRAs and heightens the accuracy of results, EPA should work with USDA to assure that PDP results for all such pesticides are reported in the most useful way or ways.

Impacts of Risk Mitigation Measures Imposed to Date

To date, the EPA has imposed dietary risk mitigation measures on just a handful of OP-food uses associated with residues found by the PDP. Based on our analysis, about 10 uses of methyl parathion have been canceled that at one time were associated with residues in food; three chlorpyrifos tolerance changes will lead to lessened dietary exposures, and there will be no impact from azinphos methyl actions taken to date.

By far the biggest impact in reducing cumulative OP risk will result from the revocation of a number of methyl parathion tolerances – especially the peach tolerance and use, by far the single dominant OP-food risk driver.

We believe the current OP-CRA is based on a modified PDP residue database reflecting EPA's expectations regarding the impact of its actions on residues of methyl parathion and chlorpyrifos. The former case is straightforward – EPA no doubt assumed that the revocation of a methyl parathion tolerance in a food in which residues were previously detected would result in no detectable residues in future years. In a forthcoming report, we will present evidence suggesting that this assumption may be overly optimistic because of the surprising prevalence of illegal residues in PDP results.

We wonder whether, and if so, how EPA adjusted existing PDP residues of chlorpyrifos in apples and grapes as a result of its decision to dramatically lower the tolerances covering these two crops. The case study is silent on such adjustments. The final OP-carbamate CRA should explicitly explain the basis and logic supporting any adjustments in PDP residue files for a pesticide impacted by risk mitigation measures. By making these assumptions and projections explicit and transparent, EPA will make it possible for all interested parties to monitor progress and determine the efficacy of the current mix of risk reduction measures.

Only in this way can the agency hope to forge over time a broad consensus that remaining cumulative OP and carbamate exposures meet the FQPA's "reasonable certainty of no harm" standard. The EPA has invested heavily in the data and methods to craft such a consensus. It will be unfortunate, and an ongoing drain on agency resources and credibility, if closure remains fleeting in the management of cumulative OP risks, given that this effort has been by far the dominant focus during more than four years of continuous effort since passage of the FQPA.

Thank you for the opportunity to share these comments. We look forward to your final report and hope that you will reflect upon our concerns and suggestions in crafting your recommendations to the agency.

Sincerely,

Adam J. Goldberg
Policy Analyst
Consumers Union

Charles M. Benbrook, Ph.D.
FQPA Consultant
Consumers Union

Carolyn W. Brickey
Executive Director
National Campaign for Pesticide Policy Reform

Shelley Davis
Co-Executive Director
Farmworker Justice Fund

Richard Wiles
Vice President for Research
Environmental Working Group

Erik D. Olson
Senior Attorney
Natural Resources Defense Council