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INSTITUTE FOR ENVIRONMENT AND AGRICULTURE
WORLD WILDLIFE FUND
ENVIRONMENTAL WORKING GROUP
FARMWORKER JUSTICE FUND
CHILDREN'S ENVIRONMENTAL HEALTH NETWORK

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COMMENTS ON EPA'S REVISED ORGANOPHOSPHATE CUMULATIVE RISK ASSESSMENT – DOCKET NUMBER OPP-2002-0154

These comments are submitted on behalf of Consumers Union of United States, Inc. (CU),[1] the Institute for Environment and Agriculture,[2] the World Wildlife Fund,[3] the Environmental Working Group,[4] the Farmworker Justice Fund,[5] and the Children's

[1] Consumers Union 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 Institute for Environment and Agriculture is responsible for policy analysis of a variety of issues including farm price supports, water contamination, closed animal feeding operations, sustainable and organic farm practices, incorporating alternatives to pesticides and safer pesticides, the implications of and regulatory structure for biotechnology and other food and environmental policies. Such information is provided to the public, the press and policy makers.

[3] The World Wildlife Fund is a non-profit organization with over 1.2 million members in the U.S. WWF is dedicated to using the best available scientific knowledge to preserve the diversity and abundance of life on Earth by conserving endangered spaces, safeguarding endangered species, and addressing global threats to the planet's web of life.

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

[5] 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.

Environmental Health Network.[6] The revised organophosphate Cumulative Risk Assessment (OP-CRA) marks a major milestone for the Agency and is the culmination of an enormous investment of Agency and scientific community resources. We commend the Agency for progress made in refining the methodologies embedded in the OP-CRA. The supporting documentation is thorough and, with a few exceptions noted below, transparent. We also are impressed by the progress made in the compilation of the food consumption and pesticide residue databases, upon which the OP-CRA rests.

We first summarize our major comments and suggestions and then present supporting data and arguments in four major sections: imposition of an added 10-X safety factor; identifying risk drivers; gaps in the exposure assessment; and, methods used in reporting results.

Summary of Comments

We strongly concur with the Scientific Advisory Panel (SAP)'s conclusions following its June 26-27, 2002, review of the EPA's 10-X decision in the revised OP-CRA (SAP Meeting Minutes No. 2002-03). A majority of panel members "concluded that the confidence with the available data was not sufficient to assure adequate protection with less than the 10x FQPA safety factor."

The reason most often cited by those SAP members supporting a full 10-X is the lack of "sufficient assurance that young children are not at substantially greater risk than adults from exposures to OPs." In the body of the report, the SAP goes further in stating that –

> "Based on this endpoint [acetylcholinesterase inhibition], there is compelling evidence to support the conclusion of potentially higher sensitivity in infants and children." [SAP Meeting Minutes No. 2002-03, page 27]

We would go beyond this tempered statement by the SAP and assert that the available evidence supports the conclusion that young animals ***are*** more sensitive to OPs across a range of biological endpoints.

In addition, the Agency has been far too patient in waiting for registrant-submitted OP developmental neurotoxicity studies. The statute provides a clear remedy in such cases – the imposition of a 10-X safety factor to minimize the chance that actual risks are underestimated because of a lack of essential data.

We also strongly concur with the SAP's judgment that EPA must take into account the full range of complex, interactive OP health effects in making a decision regarding the proper FQPA safety factor. Contrary to the statute and its own 10-X Science Policy paper, the Agency based its 10-X decision in the revised OP-CRA just on young animal-adult comparative toxicity as measured by relative BMD_{10}s for female rats. The SAP is correct in asserting that the OP-

[6] The Children's Environmental Health Network is a non-partisan and multi-disciplinary national project whose mission is to protect the fetus and the child from environmental hazards and to promote a healthy environment. The Network's three areas of concentration are education, research and policy.

CRA 10-X decision should be based on a much more comprehensive, weight-of-the-evidence-based review of OP toxicity data across multiple endpoints.

Further support for a full 10-X comes from an assessment of the "Relative Potency Factors" (RPFs) used in the revised OP-CRA. These critical values are not reliable indicators of relative OP toxicity. Ranked by acute "Population Adjusted Doses" (aPADS, which are EPA's basic measure of acute toxicity), there are five OPs that are more toxic than the reference chemical, methamidophos. When ranked according to RPFs, however, there is only one more toxic than methamidophos – disulfoton. The BMD_{10}-based method for establishing RPFs markedly understates the toxicity of several key OPs that often appear in children's foods, especially chlorpyrifos, diazinon, azinphos-methyl, phosmet, and acephate.

Uncertainty in Estimating Exposures and the Impacts of Regulatory Actions

Past CU comments and the just-released SAP report highlight the fact that relatively common high-end residues in several children's foods can result in exposures for a given child in excess of what would be regarded as acceptable – and from residues in a single food consumed during a given day.

Ongoing CU analysis of the results of the revised OP-CRA suggest that there are, in fact, several dozen OP-food combinations that will periodically result in residues high enough to put some children over their daily acceptable OP exposure level, as now defined by EPA. Assuming EPA follows the SAP's advice and restores a full 10-X in the final OP-CRA, the list of OP-food combinations posing possibly excessive daily risks from residues in a single food will grow longer.

EPA has no control over and only modest potential to predict where and when such pesticide residue "hot spots" will materialize. The only thing that is predictable is that some will occur each year in various places across the U.S. and around the globe, driven by unusually intense pest pressure and/or the collapse of once-effective pest management systems (often associated with the emergence of new and/or resistant strains of pests).

The result will be a spike of relatively high OP residues in the American diet stemming from a few crop-pesticide combinations that have never before been seen as contributing so markedly to risk. These OP "hot spots" will make attainment of the basic FQPA safety standard fleeting, and, over the long-term, nearly impossible, unless the Agency takes actions across 80 to 120 OP-crop uses to reduce the likelihood and severity of residue "hot spots."

In the revised OP-CRA, the use of dimethoate on grapes is an example of a residue-driven "hot spot." This one OP accounted for almost one-half total OP risk among one to two year olds. While we are certain that dimethoate on grapes is a major risk driver among all food-OP combinations, it would be a grave mistake to conclude that the problems posed by OP residues in the diet can be solved by phasing out this and a half-dozen other uses that, in this particular OP-CRA, account for the lion's share of risks.

This is because the revised OP-CRA results are a snapshot of a very complex landscape that can and does change dramatically with the seasons and as pest pressure waxes and wanes across different crops.

It is important to point out a strong downward bias in the revised OP-CRA results. The risk levels projected reflect "full credit" for OP risk mitigation measures taken to date. But the results are also based on an implicit assumption that farmers losing the chance to use a canceled OP will not switch to another OP. Clearly, some shift in acreage from canceled OPs to still registered ones is occurring and will continue to occur. Given the lag between use of pesticides and collection of USDA Pesticide Data Program (PDP) residue data, the results of the revised OP-CRA do not reflect the greater frequency of residues nor higher levels for OPs used more intensively in the future than in the past.

There is another source of significant uncertainty in projecting residue "hot spots." When EPA imposes risk mitigation measures in the U.S. via changes in product labels, the Agency's ability to project changes in residue profiles in imported foods is often limited. Since imported fruit and vegetables make up a large and growing portion of the national supply, EPA must rely heavily on the one regulatory tool that can and will directly impact the share of OP risk accounted for by imports – tolerance reductions.

Proper Role of OP-CRA Results in Regulatory Decision-Making

The revised OP-CRA is reliable for producing an overall sense of the magnitude of exposures and risks relative to a defined "risk cup," and hence the magnitude or scope of risk mitigation that will be needed over time to reduce risks such that they routinely fit within the risk cup.

It is vital that the guidance for conducting cumulative and aggregate risk assessments reflect the new science and data that will clearly emerge as the Agency meets the challenge of regulating based on cumulative exposures. It is a virtual certainty that new information related to down regulation of muscarinic receptors and decreased brain DNA synthesis in addition to information about inhibition of brain acetylcholinesterase will require a reassessment of the CRA in the next few years.

OP-CRA results should be updated annually, incorporating new residue data and any updated toxicological information. As a part of this process, the Agency should continue to solicit public comment.

Results of future OP-CRAs will be critical in assessing the degree of progress made, or slippage in the attainment of cumulative OP risk reduction goals. OP-CRA results should serve as an aggregate benchmark of the adequacy of risk mitigation measures imposed to date. If the desired and hoped for degree of risk reduction does not materialize, EPA should then impose another round of risk mitigation measures targeted at known-risk drivers.

At the same time, it is important that the Agency move forward to mitigate the risks that have been identified in this assessment; in particular, the Agency should move promptly to

reduce exposures to children from OP and carbamate pesticides. In so doing, it should make it clear, perhaps by granting only time limited tolerances for remaining uses, that this is a work in progress. We would like to see a schedule under which EPA will incorporate more complete data on developmental neurotoxicity and aggregate exposures to children in this cumulative assessment. In the interim, we would urge prompt and decisive action to lower exposures to OP and carbamate pesticides to children.

OP-CRA results are reliable as a "first-tier" screen in identifying almost assuredly high-risk OPs compared to OPs that contribute modestly, or hardly at all to dietary risks. EPA must rely on the results of its more detailed individual OP assessments in targeting risk mitigation interventions toward specific crop uses.

Presenting and Analyzing OP-CRA Results

We understand the importance of focusing first on risk-drivers among children ages one to two, as EPA does in reporting the results of the revised OP-CRA. Still, similar analyses and detailed results covering children two through five, and other population subgroups, will produce a different relative ranking of risk drivers. We therefore urge the Agency, when it releases the final OP-CRA results, to include detailed exposure and risk data on two to five year olds, adolescent women, women of child bearing age, and older adults.

When the Agency tests the impacts of a given decision, or potential or actual regulatory action, we request that the Agency clearly describe the baseline OP-CRA from which the impacts are being measured, as well as precisely how any underlying parameters within that baseline OP-CRA have been changed. The Agency should adopt a routine, transparent template to explain the ways past or potential future decisions/actions will be incorporated in OP-CRAs.

Carbamate Exposures Belong in the OP-CRA

Despite the clear advice from its own SAP and innumerable other expert bodies, EPA has stuck by its decision to exclude other cholinesterase inhibiting pesticides from the revised and final OP-CRA. For reasons previously presented in comments going back to 1997, we feel strongly that the preponderance of scientific evidence supports the inclusion of the carbamate insecticides in any cholinesterase inhibition-based cumulative assessment group.

The decision to exclude the carbamates is consequential. Farmers use insecticides from these two families of chemistry interchangeably, often for resistance management purposes. In most crops, carbamates leave residues about as frequently as OPs and often at comparable levels.

Unless EPA encompasses both OPs and carbamates in future CRAs, and imposes comparable risk mitigation measures across all OPs and carbamates registered for use on a particular crop, the adverse health consequences EPA is trying to prevent – cholinesterase inhibition and developmental neurotoxicity – will persist.

Detailed Comments

I. EPA Must Impose a Full 10-X Safety Factor in the Final OP-CRA

The FQPA requires the use of an additional safety factor to account for the fact that some pesticides pose greater toxicological risks to fetuses and young children, in contrast to healthy adults. According to the statute, an added safety factor shall also be imposed in cases where there are gaps or uncertainties in exposure estimates.

In carrying out the OP-CRA, EPA has reviewed and discussed extensive evidence on multiple OPs demonstrating unequivocal developmental effects, in addition to impacts on the reproductive process and many indicators of heightened toxicity to young animals (i.e., low birth weights, impacts on organ development, physiological abnormalities). Indeed, in the individual assessments of OP exposure and risk, EPA has imposed additional FQPA safety factors averaging about 4.5-X, based mostly on developmental data currently accessible to the Agency. Several key risk drivers, such as chlorpyrifos, include a full 10-X in its individual assessment.

The lack of sound developmental neurotoxicity (DNT) studies on a majority of the OPs included in the OP-CRA is, of course, a critical data gap, given the worrisome indications of developmental neurotoxicity in the studies on OPs that have been completed and submitted to date. The Agency has been far too patient in its efforts to get OP registrants to carry out and submit state-of-the-art DNT studies. The statute provides a clear remedy in such cases – the imposition of a 10-X safety factor to minimize the chance that actual risks are underestimated because of a lack of essential data. The lack of DNT data on over a half-dozen major OPs markedly strengthens the case for a full 10-X safety factor.

Uses of BMDs in Setting Relative Potency Factors

The Agency has invested much time and effort in developing the proposed "Benchmark Dose" (BMD) method for establishing RPFs. The RPFs used in the revised OP-CRA are based on 10 percent brain blood cholinesterase inhibition in female rats and are referred to as BMD_{10}s. Accordingly, the results of the revised OP-CRA are specific to a very narrowly defined biological endpoint.

Only a cursory review of other key toxicological data on OP insecticides – especially their acute and chronic Population Adjusted Doses (aPAD and cPAD) and the "No Observable Adverse Effect Levels" (NOAELs) leading to these PADs – shows clearly that the RPFs used in the OP-CRA are not reliable indicators of relative OP toxicity. Ranked by aPADS, there are five OPs that are more toxic than the reference chemical, methamidophos. When ranked according to RPFs, however, there is only one more toxic than methamidophos – disulfoton. The BMD_{10}-based method for establishing RPFs also markedly understates the toxicity of several key OPs that often appear in children's foods, especially chlorpyrifos, diazinon, azinphos-methyl, and acephate.

If aPADS or acute NOAELs were used to calculate RPFs, the results would be dramatically different. The aPAD-based chlorpyrifos RPF would be 2 and the NOAEL-based

RPF would be 0.6, instead of 0.06 based on BMD_{10}; the aPAD- and NOAEL-based azinphos-methyl RPF would be .33 instead of 0.1. Given the prevalence of residues of these two OPs in the diets of infants and children, just these changes would markedly reduce the "Margin of Exposure" (MOE) at the 99.9^{th} level of the risk distribution (or indeed any level).

While we recognize the need for the use of common endpoints or reference points in the development of cumulative risk assessments, we believe that the exceedingly narrow toxicological basis of the RPFs in the revised OP-CRA introduces substantial downward bias and uncertainty in the results of the risk assessment. EPA should respond in two ways.

First, EPA should impose a full 10-X safety factor when it carries out the final OP-CRA, given that the RPFs in the revised OP-CRA clearly and substantially underestimate risk as a statistical artifact of BMD_{10} data on female rat cholinesterase inhibition.

Second, in targeting risk mitigation measures, the Agency should look at the complete toxicological database on major OPs and the results of individual OP risk assessments to assure that the highest priority is placed on reducing exposures to those chemicals capable of producing the most serious adverse effects following low-level exposures. This sort of "weight-of-the-evidence" approach is set forth as the foundation for EPA decision-making in the science policy paper governing the imposition of the 10-X added safety factor. It is also the way the Agency has dealt with complex, uncertain issues of risk assessment methodology and interpretation over the last 20 years. We remain deeply concerned by the Agency's apparent willingness, in the case of the revised OP-CRA, to abandon this long-accepted basis for making difficult pesticide risk assessment decisions.

The FQPA's basic health-protection standard is cautious and purposefully strict. It is far stricter than the benefit-risk balancing standard that guided EPA decision-making before August of 1996. Significantly, the standard calls for a reasonable certainty of "no harm," not some low-level, but heretofore "acceptable" level of harm.

In the past, the Agency has always insisted upon at least a 100-fold standard safety factor in going from a "No Observable Adverse Effect Level" to a Reference Dose (an acceptable daily level of intake). A 100-fold standard safety factor is the functional equivalent of a MOE of 100, the exposure and risk metric the EPA uses in the revised OP-CRA.

The oral BDM_{10} for methamidophos is 0.08 mg/kg/day and this OP's NOAEL is 0.03 mg/kg/day (see Table 1.B-7 of the OP-CRA, "Points of Departure for the index chemical (methamidophos) by route of exposure for brain cholinesterase activity measured in female and male rats"). Given the way EPA has structured the revised OP-CRA, the methamidophos BMD_{10} establishes the maximum plausible size of the OP risk cup (0.0008 mg/kg/day), assuming EPA will continue to insist upon at least a 100-fold MOE.

Clearly, the methamidophos BMD_{10} allows almost three-times the exposure level as its NOAEL, the indicator of risk that EPA has typically used in setting Reference Doses. A BMD_{10} is obviously not a NOAEL. In defending use of BMD_{10}s, EPA asserts that 10 percent depression of brain cholinesterase activity is of no biological significance. While this may be true "on

average" in healthy people, it almost certainly is not true in some instances. The consequences could be considerable and negative among those with mental illness, neurological or blood disorders, or exposures to other pollutants, chemicals or drugs that affect brain function.

Given that BMD_{10}s are effect levels, and that the current OP-CRA RPFs ignore most of the toxicological data available on OP pesticides, including a large amount of data showing that some key OPs are far more toxic than suggested by current RPFs, the EPA must proceed cautiously in setting the size of the OP risk cup relative to the methamidophos BMD_{10}. Again, the statute provides a clear remedy or method to do so – imposing a full 10-X added safety factor. Alternatively, the Agency might choose to accept the Natural Resources Defense Council's suggestion in its comments to the SAP in February 2002 – that the Agency use a Benchmark Dose associated with 1 percent inhibition of cholinesterase. Such an approach would be much closer to a true NOAEL for cholinesterase inhibition among female rats exposed for 21 days or longer.

While the toxicological database on OP insecticides provides more than ample justification for a full 10-X in the final OP-CRA, exposure-side uncertainties add equally strong, additional reasons for a full 10-X, and indeed justify serious consideration of a combined safety factor on the order of 30-X to 50-X. (See Section III below for further discussion of several significant gaps in exposure data and methodologies.)

II. Identifying Risk Drivers

We were not surprised to see a relatively small number of food-pesticide combinations in the revised OP-CRA accounting for significant shares of total OP risk. Indeed, the detailed results released by EPA showed that a single use – dimethoate on grapes – accounts for some 35 percent of total risk among one to two year olds at and above the 99.8^{th} percentile of risk, and that grapes accounts for 47 percent of total risk. Two factors play major roles in driving this outcome:

- Fresh grapes are reported as eaten more frequently than any other food form, including fresh apples.

- Dimethoate breaks down to omethoate; essentially all samples with omethoate residues also contain dimethoate (the converse is not true); and EPA considers omethoate three-times more toxic than dimethoate. Taken together, "dimethoate plus omethoate" has the second highest RPF of all OPs, approximately 1.16, based on EPA's assumption that omethoate is three times more toxic than dimethoate.

Dimethoate-omethoate in fresh grapes accounts for nearly 50 percent of OP-CRA risk at the 99.8^{th} and above level, despite the fact that in recent years less than 5 percent of the U.S. crop has been treated. Mean dimethoate-omethoate residue levels in grapes fall in the 0.1 ppm to 0.2 ppm range, well less than mean residue levels in the case of other major risk-drivers, but clearly above mean residue levels in other OP-food combinations accounting for modest shares of risk.

In the revised OP-CRA, only four food-pesticide combinations account for 73 percent of total risk (dimethoate and omethoate in grapes, and azinphos-methyl in pears and apples). We do not believe these results accurately reflect the distribution of current OP risks from residues in the diet. CU's extensive analysis of OP dietary risks supports the conclusion that there are eight to 10 OP insecticides with the potential to emerge as risk drivers of the magnitude of dimethoate-omethoate in grapes in future OP-CRAs. Most of these insecticides are within an order of magnitude of dimethoate in terms of toxicity; they appear as residues just as frequently or more frequently in certain crops; and, contemporary fruit and vegetable applications routinely leave residues as high as, and in some cases higher than, dimethoate-omethoate.

These eight to 10 OPs are registered in the U.S. and are applied on four to over a dozen critical foods that collectively make up the lion's share of the diets of infants and children. Moreover, in the case of several OPs, there are a few to over a dozen additional key children's foods covered by import tolerances, in the absence of supported U.S. registrations. Accordingly, residues may appear legally in the U.S. food supply, despite the prohibition against use by American farmers.

Any one or more of several dozen supported crop-OP combinations could, in a given year, result in a residue profile sufficient to account for as much or more risk as dimethoate-omethoate in grapes in the revised OP-CRA. Based on CU's Toxicity Index (TI) values, we have begun an analysis of risk driver crop-pesticide combinations focusing both on domestically grown food and imports. We have adjusted the TI values reported in earlier reports and comments by the amount of food consumed. We use as weights 97.5th percentile consumption figures for one to six year olds, from the USDA's Continuing Survey of Food Intakes by Individuals (CSFII). These values were calculated by Novigen as input to the U.S. delegation to the Codex Alimentarius Commission.

The highest TI for an OP found in grapes is 76, and covers omethoate in imports from Chile in 1996. We adjusted this value by multiplying it by 23.6, the number of grams of grapes consumed per kilogram of body weight by the child at the 97.5th point of the grape consumption distribution. All other TI values were adjusted in the same way.

Based on this analysis, there are 30 crop-pesticide combinations posing risks greater than omethoate in grapes from Chile in 1996 – the residues largely accounting for the very large share of total revised OP-CRA risks associated with dimethoate use on grapes. The highest consumption adjusted value for omethoate in U.S. grown grapes was 17.7 from testing in 1995. There are over 135 crop-pesticide combinations that pose risks greater than the maximum value for omethoate in U.S. grapes and 225 crop-pesticide combinations within an order of magnitude of omethoate in Chilean grapes in 1996. Well-known OP and carbamate risk-driver pesticides repeatedly show up in the riskiest crop-country-pesticide combinations:

- Methamidophos
- Azinphos-methyl
- Chlorpyrifos
- Dimethoate
- Omethoate

- Methyl Parathion
- Acephate
- Methomyl
- Carbaryl
- Oxamyl

The foods-crops that appear most often are the long-recognized major kids foods including mostly fresh fruits and vegetables and fruit juices.

The crop-pesticide combinations that appear at the upper-end of lists of risk drivers like CU's or the list derived from the revised OP-CRA are based on residues actually found in recent PDP testing. But PDP testing is limited. Only a dozen to 15 foods are tested annually and some important children's foods have never been tested. Moreover, several high-toxicity OPs retain registrations and/or tolerances on several major kids foods, but fortunately, they have not been detected in food nor used widely in recent years. In some cases, the OPs are used on significant acreage, but are applied in a way and at a time that rarely if ever results in detectable residues. But EPA must acknowledge, and take steps to prevent these pesticide uses from emerging as critical risk drivers in the future. Greater than usual pest pressure, the introduction of a new pest or the loss of another pesticide to resistance or regulation can all trigger the need for farmers to spray available OPs in ways that are much more likely to lead to significant residues.

Higher than normal residues of insecticides in fresh produce tend to be triggered by three factors – the presence of intense insect pest pressure late in the season, how carefully applications are made, and the time span between fruit harvest and consumption, along with how the fruit is handled between harvest and consumption.

EPA has no control over and only modest potential to predict where and when pesticide residue "hot spots" will materialize. The only thing that is predictable is that some will occur each year in various places across the U.S. and around the globe, and that the end result will be a spike of relatively high OP residues in the American diet. Accordingly, in order to meet the FQPA's risk standard and comply with the Agency's science policies, EPA will need to take a diversity of steps impacting several dozen OP crop uses in order to both mitigate contemporary and prevent future risks. Without significant tolerance reductions and extensions of pre-harvest intervals (PHIs) on 80 to 120 uses of OP insecticides, EPA will find the FQPA's risk reduction goal to be a moving and elusive target, despite the imposition of risk mitigation measures targeted at those OP-crop uses that emerge at the top of the risk-driver list in the most recent OP-CRA.

Lack of EPA control over residue levels in imported foods is an increasingly critical issue. For example, residues on imports clearly drive dimethoate-omethoate risks in grapes. Out of the 100 highest omethoate residues found by the PDP in fresh grapes, imported samples accounted for 95. In the case of dimethoate, imports accounted for 94 out of the top 100 residues.

Need for Caution in Interpreting OP-CRA Results

As expected, based on CU's extensive past analyses of OP residues and dietary risks, grapes, apples, pears, and green beans were among the crops-foods accounting for significant shares of risk in the revised OP-CRA. Still, the results of the revised OP-CRA should be interpreted with caution, as must CU's various rankings of risk by crop-pesticide combinations. We are certain that dimethoate on grapes is a major risk driver among all food-pesticide combinations, and that among all foods, grapes surely is among the most critical for EPA to focus on. But we are equally certain that it would be a grave mistake for anyone to conclude that the problems posed by OP residues and risk can be solved by phasing out the half-dozen uses that, in any given OP-CRA, account for the lion's share of risks.

This is because the revised OP-CRA results are a snapshot of a very complex landscape that can and does change dramatically with the seasons and as pest pressure waxes and wanes across different crops. It can change markedly when there is a major crop failure in a key production region, leading to a jump in imports from some other region. Indeed, in a given crop, any of a dozen factors can combine to shift where and how pesticides are applied. These shifts, in turn, will lead to changes in residue levels and frequencies, and hence risk levels and distributions in future OP-CRAs.

It is worth restating that the method used to estimate the relative potency of OPs is one of the factors that will change the outcome of future OP-CRAs. RPFs based on the BMD_{10} measure of relative toxicity skew the assessment of cumulative OP risks in a particular way, use of aPADs would skew the results differently, as will future RPFs based on developmental neurotoxicity. There is no irrevocably correct way to measure relative toxicity in a family of chemistry like the OPs that is capable of producing such a diversity of adverse biological outcomes.

Clearly, the totality of the OP database does not support either the relative ranking suggested by EPA's RPFs, nor the magnitude of differences between various key OPs in terms of risk from comparable levels of exposure. We cannot imagine that EPA toxicologists believe that methamidophos is almost 17-times more toxic than chlorpyrifos and 10-times more toxic than azinphos-methyl, as the revised OP-CRA RPFs would suggest.

The revised OP-CRA is reliable for producing an overall sense of the magnitude of exposure and risks relative to a defined "risk cup," and hence the magnitude or scope of risk mitigation that will be needed over time to reduce risks such that they routinely fit within the risk cup. It is reliable as a "first-tier" screen in identifying almost assuredly high-risk OPs compared to OPs that contribute modestly, or hardly at all to dietary risks. Other OPs will fall between these two categories. Risk levels will be driven by actual use patterns, especially the need for late season applications on fresh produce and whether future product labels will allow such uses.

EPA must rely on additional measures and concepts in targeting and gauging the necessary scope of its risk mitigation interventions. The key variables that should be used in targeting interventions across supported uses and uses covered by import tolerances include:

- How widely the OP is used now, or might be used in the future, on a given crop, as measured crudely by the "Percent of Crop Acres Treated."

- The percent of samples tested in which residues are found ("Percent Positive"), and the relationship between "Percent Positive" and "Percent Crop Acres Treated." The higher this ratio, the greater the need for regulatory action; values under 0.1 suggest that 90% or more applications are not resulting in detectable residues.

- The mean level of all samples in which a residue was found ("Mean Residue").

- The "Reference Concentration," or RfC, which is the amount of a pesticide in a given food that would deliver to a person of known weight their personal acute Reference Dose of the pesticide. As a matter of policy, CU has argued in past comments that no tolerance should be set over the RfC, and indeed for chemicals with multiple uses, we have suggested that tolerances should typically be set no higher than one-tenth the RfC based on realistic exposure patterns (i.e., a 44-pound five year old consuming one medium sized apple).

Other things equal, the need for tolerance reductions is greatest for food-chemical combinations where the tolerance exceeds the RfC by a wide margin. Some do so by three orders of magnitude. The urgency and extent of needed changes in use patterns should be driven by two factors.

First, the current and recent-past frequency of residues and by how close upper-end residues are to actual RfC levels. There are relatively few crop-pesticide combinations where high-end residues exceed one-tenth of RfC values. These are unequivocal risk drivers and warrant immediate regulatory interventions, beginning with substantial tolerance reductions and extensions of PHIs.

Second, EPA must take a series of actions to truncate the potential for risk trading, as regulations constrain the use of certain OPs, leading to predictable increases in the use of others. Carbamate insecticides are also likely to be used more aggressively as once-popular OPs are phased out. Since these insecticides also inhibit cholinesterase activity and should be included in future OP cumulative assessments, the Agency must extend its efforts to limit risk-trading to the widely used carbamate insecticides methomyl, carbaryl, oxamyl, carbofuran, aldicarb, and formetante hydrochloride.

Need to Widen Analysis to Capture All Risk Drivers

We understand the importance of focusing first on risk-drivers among children ages one to two, as EPA does in reporting the results of the revised OP-CRA. Still, we are sure that a similar analysis covering children two through five will produce a somewhat different relative ranking of risk drivers. Clearly children three to five consume many foods that they never or rarely ate as one or two year olds. Inevitably, some of these foods will emerge as risk-drivers.

Accordingly, when presenting the results of the final risk assessment, we urge the Agency to, at a minimum, produce the same sort of detailed Excel workbook with results by pesticide-food combination, and then aggregated by food and by pesticide as it has done with the revised assessment, for both one to two year olds and two to five year olds. Indeed, perhaps up to three or four additional DEEM runs should be routinely reported focusing on adolescent women, women of child bearing age, and older adults, particularly more vulnerable senior populations.

In addition, the revised assessment adequately reflects the level and distribution of OP risks across the general population but does not reflect consumption patterns, and hence risk among ethnic groups or people with certain dietary preferences. Vegetarians are an obvious example, as are Hispanics and Asian individuals and people with food allergies. In the future, EPA should conduct additional OP-CRAs for these and other subpopulations in order to determine whether any additional foods and pesticide-crop combinations emerge as significant risk drivers in need of risk mitigation measures.

III. Gaps and Uncertainties in Assessing Exposure and Risk

Several exposure data gaps and methodological uncertainties raise questions regarding the completeness and accuracy of OP dietary exposure profiles. In nearly all cases, the likely impact of a data gap or methodological weakness is underestimation of risks, particularly to certain subpopulations.

Need for Transparency When Adjusting Processing Factors

EPA has decided to rely upon adjustments in processing factors as a basic, if not the basic method for building the impacts of regulatory decisions into OP-CRAs. This method is conceptually and technically simple, and retains the integrity of the underlying residue database. For example, residues of chlorpyrifos in apples, grapes and tomatoes were eliminated in the revised OP-CRA by assuming a "zero" processing factor for both fresh and all processed products derived from these crops. The grape and apple uses of chlorpyrifos continue, with the tolerance reduced to 0.01 ppm and greatly extended PHIs.

The justification for the assumption that chlorpyrifos residues in apples and tomatoes will be zero was not presented in the documents, nor was the method for making the adjustment in risk levels made transparent. In recent years chlorpyrifos has been sprayed on about one-quarter of apple acres and 5-10% of tomato acres. Use abroad is heavier in some countries shipping produce to the U.S. In 1999, chlorpyrifos residues were found in 24% of apple samples tested, at a mean value of 0.022 ppm. Clearly, many U.S. growers have been using chlorpyrifos in ways that will keep residues below 0.01 ppm.

In the future, EPA should be explicit in identifying where, how, and why processing factors have been adjusted to reflect EPA's expectations regarding the impact of regulatory actions already imposed or scheduled to come into effect. For example, in Appendix III, C., 5, "Processing Factors Used in Estimating Residues of OP Pesticides in Food Commodities," the processing factor for chlorpyrifos on all apple and tomato food forms is zero, despite the fact

these uses are supported. For supported uses, it is not possible to tell whether a processing factor reflects actual data on degradation or dissipation of residues during processing, or EPA's projection of the impacts of regulatory actions. This short-coming should be rectified by the routine publication of a second processing factor table highlighting all cells where EPA has adjusted a processing factor as a result of a past or planned regulatory action or for any other reason. This table should make explicit the adjustment, as well as the analytical and evidentiary basis for the magnitude of the adjustment.

There are, in addition, questionable assumptions embedded in the processing factors used in the revised OP-CRA. Examples follow.

Azinphos-methyl – EPA has reported 13 supported uses of azinphos-methyl, each of which is covered by an existing tolerance. Several uses and tolerances are time-limited or scheduled for phase out over four years. EPA assumes non-zero processing factors, however, for just four crops and foods derived from these crops – apples, pears, Brussels sprouts, and cherries. Nine of the 13 continuing uses are thus not included in the revised OP-CRA.

Moreover, EPA has not taken actions to cancel some 20 additional azinphos-methyl tolerances associated with non-supported uses. Many of these tolerances cover uses on key children's foods like peaches, green beans, citrus products, melons, nearly all berries, and tomatoes, and remain on the books as import tolerances. Accordingly, residues from just four azinphos-methyl uses out of a possible 30-plus uses are included in the revised OP-CRA, a factor that significantly underestimates exposure and risk associated with this widely used OP. Moreover, given that tolerances have been canceled or reduced for other key OPs applied to treat the same insects in many of these crops, EPA should anticipate a moderate to significant shift in acres treated to azinphos-methyl abroad, as long as tolerances remain on the books.

Methamidophos – while only potatoes and tomatoes are supported in the U.S., several tolerances will apparently remain on the books covering imports. In some of these crops/foods, EPA assumes processing factors of zero, while in others, factors between zero and one are used. For example, EPA assumes zero residues in broccoli, cabbage, cucumbers, eggplant, leafy lettuce, melons, but non-zero factors for Brussels sprouts and peppers.

Mevinphos – while there are no supported U.S. uses, several key import tolerances are supported and will continue to allow mevinphos use on crops ultimately exported to the U.S. Appropriately, EPA has imposed a processing factor of one covering mevinphos in fresh grapes and raisins, yet without explanation assumes a zero value for grape juice. Why does EPA assume that companies shipping grape juice concentrate to the U.S. will source grapes not treated with mevinphos?

Phosmet – EPA uses a processing factor of 0.05 for phosmet in several forms of cooked apple products, far lower than the processing factor applicable to azinphos-methyl residues. The scientific basis for the unexpectedly low processing factor for phosmet in certain processed foods warrants critical assessment given the expected substantial increase expected in the use of this OP.

EPA Must Address When and How to Project Reductions, Increases and Net Changes in OP Risks as Use Patterns Shift

The revised OP-CRA fully integrates the risk mitigation entailed in revoked tolerances and phased out uses, yet does not make an attempt to adjust other exposures upward for the inevitable increase in the use of other, supported OPs. Accordingly, there is now a downward bias in the results of the OP-CRA, a bias that will become more pronounced as more uses are impacted by regulatory actions and voluntary cancellations.

EPA analysts lack a method to project the impact of changes in tolerance levels and/or PHIs and use rates on the frequency and distribution of residues, and hence lack a method to project the impact of regulatory actions that fall short of cancellation/tolerance revocation. Likewise, EPA lacks a method to project the magnitude and consequences of risk trading, despite the fact that a degree of risk shifting is inevitable.

EPA's ability to project changes in residue profiles as a result of changes in use patterns and tolerance levels is complicated by the fact that such changes in U.S. regulatory status have no direct bearing on how pesticides are used abroad. EPA has no way of projecting the impact of such actions on residues in imports. Since imported fruit and vegetables make up such a large portion of the national supply during certain off-season months, uncertainty over the changes in residues in response to regulatory actions, short of cancellation, is another major factor supporting a full 10-X uncertainty factor in the final OP-CRA.

Imports Likely to Account for a Growing Share of Cumulative OP Dietary Risk

In 1980, imported fresh and frozen fruits accounted for 5.8 percent of U.S. consumption, rising to 21.8 percent in 2000 ("The Import Share of U.S.-Consumed Food Continues to Rise," Alberto Jerardo, Economic Research Service, U.S. Department of Agriculture, FAU-66-01, July 2002).

In a few key commodities growth has been even more dramatic. In 2000, 44.3 percent of fresh and frozen grapes were imported, up from 12.6 percent in 1980. In reality, this means that most Americans consumed 80-100% imported grapes for perhaps about 3 to 5 months, and a lesser but significant share for up to another three to four months, and mostly domestic grapes the remainder of the year. Over 60 percent of apple juice is now imported, and just under 60 percent of asparagus. Almost 15 percent of potatoes are now imported, up from just over 1 percent in 1980.

In recent years the residue profile in imported fresh produce has, in some cases, gotten much worse relative to U.S.-produced food. CU has documented, for example, the significant progress in reducing high-risk residues in fresh market tomatoes produced in Florida, while risks have actually increased in the same time period in tomatoes produced in Mexico. (See Table 6 in the June 2000, Consumers Union report "Update: Pesticides in Children's Foods," accessible at http://www.ecologic-ipm.com/PDP/Update_tables.html).

As discussed above, residues in imported grapes account for almost all the high-end exposures leading to the large share of total OP-CRA risk accounted for by dimethoate and omethoate in grapes. Imports account for about half the top 100 omethoate and dimethoate residues found in apple juice samples, despite the fact that over the three years apple juice has been tested by the PDP, there were a total of 1,103 domestic samples and 291 imported samples. The same point applies to methamidophos in tomatoes; there have been about two domestic samples for each imported sample, yet imports still accounted for 41 of the top 100 residues.

Do Other Cholinesterase Inhibiting Pesticides Belong in the OP-CRA?

Despite the clear advice from its own SAP and innumerable other expert bodies from the National Academy of Sciences to the International Life Sciences Institute, EPA has stuck by its decision to exclude other cholinesterase inhibiting pesticides from the revised and final OP-CRA. For reasons previously presented in comments going back to 1997, we feel strongly that the preponderance of scientific evidence supports the inclusion of the carbamate insecticides in any cholinesterase inhibition-based cumulative assessment group.

The decision to exclude the carbamates is highly consequential. Farmers use insecticides from these two families of chemistry interchangeably, often for resistance management purposes. Any factor – regulations, resistance, price changes, availability, the preference of IPM advisors – that reduces the use of products in one class almost invariably increases use of products in the other. For almost every risk-driver OP use, there are one or two registered carbamates that are typically used for exactly the same reasons in about the same ways. In most crops, carbamates leave residues about as frequently as OPs and often at comparable levels. For these reasons, the risks stemming from treating an acre of apples or green beans with the OP azinphos-methyl are not that different than if the same orchard or field was treated at the same time with the carbamates methomyl or oxamyl.

Unless EPA encompasses both OPs and carbamates in future CRAs, and imposes comparable risk mitigation measures across all OPs and carbamates registered for use on a particular crop, the adverse health consequences EPA is trying to prevent – cholinesterase inhibition and developmental neurotoxicity – will persist despite the fact that the impacts will be caused by a different mix of insecticide active ingredients. The Agency needs to focus on high-risk use patterns, as opposed to just the particular OP that is currently used more heavily on a given crop, resulting in the most worrisome residue profile.

Illegal Residues Belong in Future OP-CRAs

We are pleased to see that EPA accepted our arguments in support of including illegal residues in the revised OP-CRA. The Agency states that these residues contribute modestly to total risks in the current assessment. Based on our analyses, we suspect that illegal residues are accounting for at least 5 percent, and perhaps as much as 10 percent of total OP dietary risk. We also suspect this share to increase as EPA begins to impose tolerance reductions across a wider array of OP crop uses, as it surely must to meet the FQPA's stricter safety standard.

In future OP-CRAs, we suggest that EPA include in the standard tables reporting results a table that shows the percent of total risk by crop, and by pesticide accounted for by illegal residues, along with the pesticide-crop combinations falling in this category.

IV. Method Used to Report Detailed Results

We greatly appreciate the Agency's decision to present the detailed results of the OP-CRA in a form that allows assessment of what we have called the "excess risk pool" – exposures to children at the upper-end of the risk distribution. In our March 2002 comments, we had requested that EPA present the results of the revised assessment by food-pesticide combination, focusing on the tail end of the exposure-risk distribution. We were delighted to see Appendix C.8, which sets forth the detailed DEEM-FCID CEC ("Critical Exposure Contribution") Report. This Appendix presents a summary of the daily exposure records between the 98th and 100th percentile of the risk distribution for children aged one to two.

We applaud the EPA decision to focus on risk-drivers at the 99.8th to 100th percentile of the distribution. Moreover, we commend the Agency for the forethought invested in designing the useful and adaptable Excel-based workbook that makes up Appendix C.8. We found the data to be easy to work with. It allows analysts to ask and answer a far wider range of questions then previously possible. We urge EPA to continue to report the results of future OP-CRAs in this same format. We are aware that the Agency is carrying out a number of analyses of different science policy and risk mitigation measures, and also urge that results from these simulations be presented in full detail, in the same way.

Reporting Future OP-CRA Results

When the Agency tests the impacts of a given decision or potential or actual regulatory action, we request that the Agency clearly state and fully describe the baseline OP-CRA from which the impacts are being measured, as well as precisely how any underlying parameters within that baseline OP-CRA have been changed. The Agency should adopt a routine, transparent template to explain the ways past or potential future decisions/actions will be incorporated in OP-CRAs. The template should include all parameters or equations modified; all adjustments made in underlying processing factors and/or residue databases; any changes in uses encompassed; the actual empirical changes made; and, the justification for the changes made.

In terms of transparency, our only criticism of the revised OP-CRA is the lack of a clear explanation in any of the documents regarding how the Agency incorporated past regulatory actions impacting OPs such as methyl parathion, chlorpyrifos, and azinphos-methyl. While we could find no documentation of how the Agency built the impacts of past actions into the revised OP-CRA, we were able to reach technical experts in the Agency who provided clear and complete explanations. In most cases, the Agency has adjusted the processing factors applied to various food form-pesticide combinations to incorporate the expected outcome of regulatory actions. We consider this a logical, and in most instances, appropriate way to do so.

We support the Agency's plan to include among the documentation accompanying the final OP-CRA an appendix describing these changes and indeed, when future OP-CRA results

are released, they should also include a transparent description of changes made, and why. Appendix II, C. 5 presents the processing factors used in the revised OP-CRA. If and as processing factor adjustments are used to integrate regulatory actions into a OP-CRA, the Agency should present a second table, organized much like Appendix III, C, which presents the adjustments made in various processing factors. There should be an accompanying narrative explaining the basis for each adjustment, including how the Agency decided upon a quantitative reduction of X percent in cases where regulatory actions fall short of cancellation.

As the Agency carries out a range of sensitivity analyses, testing the impacts of potential or actual regulatory actions, it will become increasingly difficult to sort out the individual and combined impacts of all actions taken to date, plus those under consideration. Accordingly, we urge EPA to develop a "minimum dataset" of descriptive statistics that will be routinely reported in order to explain how the level and distribution of risks have changed from previous OP-CRAs. These statistics may also need to be expressed relative to more than one baseline. The Agency will have to be careful and thorough in explaining what the results of a given OP-CRA actually mean relative to various baselines, such as risks when the FQPA was passed in July 1996, exposure/risks at the time the first major round of actions were taken (August 1999), and risks upon completion of the first-round of actions across all OPs, for example. As the Agency contemplates the need for further actions, it will be useful and necessary to assess impacts relative to several baselines, in order to place in the clearest possible perspective the actual impact of a pending action.

Appendix C.2 reports the residue values of OP insecticides in various foods that were included in the revised OP-CRA. We applaud the Agency for providing this useful summary table, but request that when the final OP-CRA is released, that this table be augmented by additional columns – "Mean Residue," "95th Percentile Residue," and "97.5th Percentile Residue." The table now reports an average residue value across all samples tested; this average includes all the zero values, plus the quantified, positive residue values. This "average" is somewhat meaningless, however, since it is impossible to sort out the impact of the number of zeros from the actual distribution of the residues. Accordingly, we urge the Agency to add another column with the mean, or average, of just the positive values. To give a bit more insight into the distribution of residues, we also request that EPA add columns reporting the 95th and the 97.5th level in the distribution of residues. The later request is to help compare residue levels in the U.S. to other countries. The World Health Organization, via work in the Codex Alimentarius Commission, is compiling residue data from several countries of the world. They have asked countries to identify the 97.5th level of residues, as a method to assess "high-end" exposures.

With the requested, added columns, analysts will have a much better understanding of the distribution of residues across various food-chemical combinations. In addition, the residue data in the EPA OP-CRAs can more readily be compared to residue data from other countries.

Conclusion

Thank you for the opportunity to offer these comments. We look forward to release of the final methodology later this year and are especially eager to see the first full set of results and what the Agency proposes to do to bring them into accord with the FQPA's new standard.

Sincerely,

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