USDA

United States Department of Agriculture

Research, Education, and Economics
Agricultural Research Service

January 5, 2016

Richard Keigwin, Director
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs, Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Re: USDA Public Comments on the Chlorpyrifos; Tolerance Revocations, a proposed rule published in the Federal Register on November 6, 2015; EPA docket identification (ID) number EPA-HQ-OPP-2015-0653

Dear Mr. Keigwin:

The United States Department of Agriculture appreciates the opportunity to comment on EPA's proposed rule to revoke all tolerances for the insecticide chlorpyrifos which was published on November 6, 2015 in the Federal Register. This proposal will have serious impacts to U.S. agriculture which are described briefly below and in detail in attached comments. In addition, USDA is very concerned about the underlying foundational materials and methods that led to this determination. Many of these concerns were conveyed to EPA in USDA's public comments posted in April 2015. As requested in the November 6, 2015 Federal Register Notice, we are resubmitting them with our comments on the proposed tolerance revocation for your review and reconsideration.

By revoking all tolerances, but not suspending or cancelling the registration of chlorpyrifos, EPA implies that growers may continue its use because EPA does not expect measurable residues on commodities produced using chlorpyrifos when label directions are followed. Failure to cancel means that growers may legally use this insecticide. But, EPA's proposal to revoke all tolerances prior to any cancellation action would place end-users (farmers, etc.) in the position of potentially producing a crop with illegal residues from the legal use of a pesticide. They could face enforcement actions under the Federal Food, Drug, and Cosmetic Act (FFDCA) if the Food and Drug Administration (FDA) were to detect residues on food produced after EPA revokes all tolerances. USDA strongly objects to a proposed action which places growers who use chlorpyrifos at risk of violating the food tolerance provisions of the FFDCA. We request that EPA fully review the scientific, procedural, and economic concerns as outlined in USDA's comments before implementing any action that compromises U.S. agriculture.

Chlorpyrifos is an important pest management tool that has been successfully used for over fifty years. It is incredibly important to U.S. agriculture and related industries as it is often the key defense against numerous unpredictable pests. Maximum residue limits (MRLs) for citrus are critical because a significant percentage of the crop is exported (20-40%). Because chlorpyrifos was registered many years ago, MRLs have established for a long time. For newer chemistries, this is not the case and pesticide manufacturers are currently working to prioritize active

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ingredients within Codex and in specific countries (Korea, Japan, Taiwan, etc.) A blanket cancellation of tolerances will disrupt trade with numerous international partners.

Finally, in response to the EPA-BEAD document titled **"Analysis of the Small Business Impacts of Revoking Chlorpyrifos Food Tolerances"**, USDA, in general, does not agree with the conclusions drawn from the economic analysis provided for the "no SISNOSE" determination. Moreover, EPA's analysis has not been adequately reviewed by USDA. USDA requests that all the data EPA used in the determination of "no SISNOSE" be available for review by USDA to confirm that EPA has adequately interpreted the agricultural data on pesticide use.

USDA's detailed comments are attached and note that USDA may be providing more comments later in response to the EPA document entitled, ``Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides" which will also have bearing on chlorpyrifos.' As always, USDA is glad to work in advance with EPA on all issues that potentially impact agriculture. Please let me know if you would like to discuss.

Sincerely,

Sheryl H. Kunickis

Sheryl H. Kunickis, Ph.D.
Director

Part A. USDA Comment on EPA Proposed Rule "Chlorpyrifos; Tolerance Revocations"

EPA is proposing to revoke all tolerances of the insecticide chlorpyrifos, because "EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information, are safe." EPA arrived at this conclusion by comparing the expected food, residential, and drinking water chlorpyrifos exposure to the population adjusted dose (PAD). The PAD is derived by dividing the toxicological point of departure by applicable uncertainty and safety factors, including the FQPA safety factor.

USDA has concerns both with how EPA calculated the PAD, as well as the overly conservative assumptions made in calculating the expected exposure to chlorpyrifos. As a result, the PAD is lower than it should be, while the estimated exposure to chlorpyrifos is higher than it should be, which leads to the mistaken conclusion that chlorpyrifos, as it is currently used, is unsafe.

1. EPA Should Improve and Further Refine its Estimates of Chlorpyrifos Exposure

The risk assessment could be further refined. The aggregate assessment finds exposures from food, residential use and drinking water to be above the levels of concern for some vulnerable population groups. It is unclear which foods may be risk drivers, as well as unclear which dermal exposure scenarios in combination with food contribute most to the total exposure. Because the drinking water exposure "fits" into the remaining area of the risk cup after accounting for these other exposure sources, there should be some discussion of the sensitivity of the aggregate model to particular input data used in the dietary and residential assessments. If the residential exposure is the result of a specific set of assumed scenarios, it would be clearer if the Agency provided a sensitivity analysis showing how results might differ if other input data from other scenarios were used. The drinking water risk assessment relies on estimated surface water concentrations – this likely overestimates exposure when community drinking water systems provide water as some of the residue or degradation product will likely be removed due to treatment. Assuming treatment at the highest application rates of all possible crop acres where chlorpyrifos is registered is overly conservative and could be refined, perhaps using data sets such as the California pesticide use data, to include a more representative typical crop treated scenario. With all of the various assessments, providing estimates of uncertainty about the results would provide additional information.

These types of watershed analyses should also include monitoring data or other empirical measurements of chlorpyrifos to provide some evaluation of the ability of the modeling approaches used to simulate actual observed in-stream concentrations. There are many types of uncertainties inherent in watershed simulation. Verification that the modeling approach is reliably able to simulate the behavior of chlorpyrifos concentrations in lotic or lentic environments would increase confidence in the drinking water exposure assessment. Further

analysis of monitoring data from finished drinking water samples from community water systems would provide real-world data on actual exposures. More explanation is needed for the Agency's drinking water intake database for identification of vulnerable community water systems. The assumption that a portion of the watershed is treated will influence the estimation of chlorpyrifos concentrations in surface water. This will be difficult to determine in States other than California, the only State where pesticide usage is recorded by crop for individual users. Assuming all registered use patterns undergo treatment during the same year or season will overestimate exposure.

Finally, the USDA Pesticide Data Program (PDP) has sampled groundwater and drinking water for chlorpyrifos, including at school and daycare wells, for the past 15 years. No chlorpyrifos was detected in hundreds of water samples in 2010-13 at the parts per trillion level. USDA suggests that PDP water data be used in the chlorpyrifos analysis instead of the overly conservative modeling estimates. Alternatively, these monitoring results should at least call into question the validity and reliability of the modeled estimates, and should lead EPA to reconsider its modeling approach.

2. Revocation of Tolerances is the Wrong Vehicle for Local or Regional Risk Mitigation

Revoking nationwide tolerances based on drinking water concentrations is a blunt tool that can't distinguish between regions or watersheds where chlorpyrifos does not exceed aggregate risk values versus those where drinking water is an important contributor to risk values in excess of the level of concern. In such situations, changing the use patterns on the label provides a more targeted mitigation than nationwide removal of all food tolerances. Unless the risk mitigation actions are to be conducted on a watershed basis, using a watershed or community water system as the geographic scale for the drinking water risk estimation is likely to mischaracterize the risk when considered at a national or regional scale. Using watershed analysis as the basis for a nationwide tolerance revocation results in extrapolating a risk mitigation action relevant at a watershed level to a much broader geographic scale where the simulated exposure via drinking water does not uniformly warrant mitigation.

3. EPA Should Reduce the 10X FQPA Safety Factor

USDA encourages EPA to reconsider the retention of the default 10X FQPA safety factor for infants, children, youths, and women of childbearing age, which had been reduced to 1X for most exposure routes in the 2011 Preliminary Human Health Assessment. The primary purpose of the FQPA safety factor is to address inadequacies or gaps in required studies or when important data needed to evaluate risks to children are missing or inadequate ("Determination of the Appropriate FQPA Safety Factor(s) in Tolerance Assessment," Office of Pesticide Programs, U.S. Environmental Protection Agency, Feb. 28, 2002). USDA believes that no significant data deficiencies exist in this case, and that therefore EPA should not be precluded from reducing the

10X FQPA safety factor. At a minimum, EPA should identify specific inadequacies or gaps in any required studies or explain which needed data are missing or inadequate.

The points of departure in this assessment are derived from PBPK-PD modeling and are modified by data-derived extrapolation factors (DDEF), as opposed to a traditional approach encompassing a NOAEL and uncertainty factors. EPA's ability to use PBPK-PD modeling and DDEF demonstrates how comparatively data-rich its situation is when addressing chlorpyrifos. As a result of the many years of thorough study and evaluation of chlorpyrifos, it is inappropriate to use the default 10X FQPA safety factor which is intended for assessments with significant data deficiencies.

The purpose of the FQPA safety factor is to account for uncertainties present in the relationship between an adverse outcome observed in research studies (usually quantified in a point of departure) and a *corresponding* acceptable human exposure level (such as a population adjusted dose). In this assessment, EPA is evaluating two separate adverse outcomes: 10 % inhibition of RBC AChE and the neurodevelopmental effects potentially detected by the Columbia Study. The 10X FQPA safety factor is ostensibly *justified* due to uncertainty associated with the neurodevelopmental effects, but it is then *applied* to the point of departure based on 10 % inhibition of RBC AChE. This point of departure is based on extensive data and research, and does not contain any of the uncertainties that would usually require an FQPA safety factor greater than 1X.

If EPA could substantiate the connection between exposure to chlorpyrifos and the neurodevelopmental effects observed in the Columbia Study, and could calculate a point of departure for these adverse outcomes, it might be appropriate to apply uncertainty and safety factors to this new neurodevelopmental point of departure. However, the sole reliance on and current limitations of epidemiologic studies, which do not provide a clear understanding of exposure, dose-response, or mode of action/adverse outcome pathway, do not allow such a point of departure to be calculated. These same, limited epidemiologic studies should not be used to justify the addition of an FQPA safety factor to the much more robust 10 % inhibition of RBC AChE point of departure.

4. Application of FQPA Safety Factor to Occupational Risk Assessment

USDA notes that the use of a 10X safety factor employed in the chlorpyrifos risk assessment was incorporated into the occupational assessment for chlorpyrifos. EPA should explain its authority for using an FQPA safety factor to conclude whether *occupational* exposure to chlorpyrifos is unsafe. USDA is concerned that the application of an FQPA safety factor to occupational exposure (as opposed to aggregate exposure due to food, drinking water, and non-occupational residential exposure) is beyond the scope of the requirements of the Food Quality Protection

Act. During the Registration Review effort, EPA had appropriately adhered to the FQPA requirements by combining exposures from only dietary, residential, and drinking water sources.

5. Concerns over the Proper Use of Epidemiological Studies

Basing application of an additional FQPA safety factor on epidemiological evidence appears to be a novel application. Previously the FQPA safety factor was justified by such factors as the completeness of the toxicity database, the type and severity of the effect observed, and the nature and quality of the available exposure data and other data required in Part 158. The use of epidemiological data to this end has not been well discussed. It would be more transparent if EPA developed a new standard operating procedure for using epidemiological data when deriving a FQPA safety factor and convened an expert panel to review the SOP.

USDA was unable to locate a standard operating procedure applicable to the use of epidemiological studies when setting the FQPA safety factor, although we did find the 2010 Draft Framework for incorporating Human Epidemiologic & Incident Data in Health Risk Assessment. Among the key guidance documents relied upon by the Agency in the table on page 9 of this Draft Framework is the Food Quality Protection Act 10X Safety Factor document, which does not include any discussion of the use of epidemiological data to support the FQPA safety factor. If epidemiological studies are to form the basis of the FQPA factor, a new standard operating procedure is needed.

During development of new risk assessment methodologies and practices following passage of the Food Quality Protection Act, the EPA provided guidance in a series of science policy papers. Here, the methodology is presented in the Revised Human Health Risk Assessment (RHHRA) and not in a stand-alone science policy paper available for public comment. Comments on the RHHRA and the methodology for identifying relevant epidemiological studies that support derivation of the FQPA safety factor have not been addressed by the EPA. The RHHRA does not adequately address the reservations expressed by the 2012 Scientific Advisory Panel on Scientific Issues Associated with Chlorpyrifos Health Issues. The RHHRA, on page 27, states that a mode of action (MOA) adverse outcome pathway (AOP) leading to neurobehavioral events resulting from exposure to chlorpyrifos cannot be established.

In a January 25, 2013, letter to representatives of the Natural Resources Defense Council and the Pesticide Action Network North America, the Director of the EPA Office of Pesticide Programs at the time, Dr. Steven Bradbury, outlined significant concerns the Agency had about the quality and relevance of the epidemiological studies. USDA asks that EPA clarify how exactly these concerns were addressed to EPA's satisfaction. If they were not addressed, EPA should explain why the issues raised by Dr. Bradbury are no longer of concern to the Agency.

Specifically, USDA requests EPA's response to the following statements by Dr. Bradbury:

"Before EPA decides how to use the epidemiological data on chlorpyrifos, we believe it is critical to attempt to resolve questions about these studies regarding the extent of the cohort members' exposures to chlorpyrifos, as well as the impact of exposure to other compounds capable of causing or contributing to the observed neurological outcomes."

"In order to complete both the dose reconstruction and analyses on other chemical exposures, however, we will need to analyze the original data ("raw data") from the Columbia University study to better understand the exposure to chlorpyrifos and other chemicals. To date, the study authors have declined our request to provide that information to us..."

USDA requests that the data underlying the foundational epidemiologic studies supporting EPA's human health risk assessment for chlorpyrifos be procured by EPA and released for expert peer review. Many of the Agency's cited studies were federally funded and the data should be made available. It is not clear to USDA why the data has not been released to date. The protection of Personally Identifiable Information (PII), or Sensitive Personal Information (SPI) is a common practice in the health research profession so this should not be an issue. Because of the precedent-setting nature, EPA's strong reliance on epidemiologic data to support its conclusions for chlorpyrifos, and the future implications for other organophosphates and other pesticide classes, it is imperative that the data be made available for peer review by experts, so as to assure sound science and statistical robustness.

6. Deficiencies in the Methodology of the Epidemiological Studies

In addition to the concerns about the availability of underlying data mentioned above, USDA would also like to highlight specific issues that might not have been addressed in the epidemiological studies which EPA used to justify the addition of a 10X FQPA factor.

- Was the statistical approach sufficiently robust? Were sample sizes large enough for lead, PAH and other contaminants? With the data from the cohort studies in hand, a robust statistical analysis can be undertaken to determine if the sample sizes for lead levels and polycyclic aromatic hydrocarbons (PAH) were robust enough to be ruled out as confounding factors. It is well known from current literature that lead and PAH levels in New York City have been at high levels and are of neurotoxic and birth weight concerns. Exceedances in lead blood levels were declining over the same study period for chlorpyrifos (1999 – 2005). For example, cord-blood lead concentrations were available for only 28 study children in one study.
  http://www.pnas.org/content/109/20/7871.short
  "Brain anomalies in children exposed prenatally to a common organophosphate pesticide"
  "Umbilical cord-blood lead concentrations were available for a subset (n = 28) of study

children (13 higher exposure; 15 lower exposure) and a subset of the larger cohort (n = 202)."

- Were the appropriate statistical techniques employed? "For example, in relation to limitations of data on exposure in the epidemiological studies, a Panelist noted that despite a fairly high portion of the samples whose results were below the limit of detection or quantification for whatever was being analyzed, little use was made of techniques to integrate non-quantified samples into the statistical test." (Page 57, SAP).
- While study authors sought to link birth outcome to a decline in the residential use of chlorpyrifos, USDA notes that chlorpyrifos use in major foods (tomatoes, apples) were cancelled during the time period and application rates were lowered.
- Were Other Confounding Factors Adequately Considered?
    - Environmental Contaminants from the 9/11 World Trade Center Event. The events of 9/11 was a major environmental event which took place in New York City which resulted in lower birth weights for children born in a two mile radius around the World Trade Center. Besides lead, and PAHs, phthalates could play a role in birth outcomes. An analysis of where Columbia study participants resided relative to the World Trade Center could be informative to linking birth outcomes to contaminants other than chlorpyrifos.
      http://www.ncbi.nlm.nih.gov/pubmed/15579426
      "The effects of the World Trade Center event on birth outcomes among term deliveries at three lower Manhattan hospitals."
      "The effects of prenatal exposure to pollutants from the World Trade Center (WTC) disaster on fetal growth and subsequent health and development of exposed children remain a source of concern." "Term infants born to women who were pregnant on 11 September 2001 and who were living within a 2-mile radius of the WTC during the month after the event showed significant decrements in term birth weight (-149 g) and birth length (-0.82 cm), compared with infants born to the other pregnant women studied, after controlling for sociodemographic and biomedical risk factors. The decrements remained significant with adjustment for gestational duration (-122 g and -0.74 cm, respectively). Women in the first trimester of pregnancy at the time of the WTC event delivered infants with significantly shorter gestation (-3.6 days) and a smaller head circumference (-0.48 cm), compared with women at later stages of pregnancy, regardless of the distance of their residence or work sites from the WTC. The observed adverse effects suggest an impact of pollutants and/or stress related to the WTC disaster and have implications for the health and development of exposed children."
      http://www.ncbi.nlm.nih.gov/pubmed/18500713
      Mt Sinai J Med. 2008 Mar-Apr;75(2):129-34. doi: 10.1002/msj.20032.
      "Impact of September 11 World Trade Center disaster on children and pregnant women." "A Columbia research team examined pregnancy outcomes in 329 women who lived, worked or gave birth in lower Manhattan in the 9 months after September 11; they found that these women gave birth to infants with

significantly lower birth weight and shorter length than women living at greater distances from Ground Zero."

- Effect of Polycyclic Aromatic Hydrocarbon Versus Chlorpyrifos.
  http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2864932/
  "Prenatal Airborne Polycyclic Aromatic Hydrocarbon Exposure and Child IQ at Age 5 Years"
  "Prenatal exposure to lead (mean ± SD: 1.06 ± 0.74 μg/dL), maternal active smoking (measured as cotinine levels), and *chlorpyrifos levels were not significant predictors of IQ* in this sample (all P>.1)"
  "As discussed above, previous results from this cohort indicated that exposure to PAH air pollutants in New York City during pregnancy is a risk factor for developmental delay at age 3, as identified with the Bayley Scales of Infant Development.26 *The present analysis suggests continued effects of prenatal PAH exposure on child IQ at age 5.*"

- Analytical Methods. USDA also believes it is critical that all the analytical methods used in the cited studies be validated and are able to be replicated. USDA is concerned if replicate determinations of analyte recovery from a given matrix (substrate) down to the stated LOD were not carried out as per EPA standard analytical guideline requirements. Because chlorpyrifos and OP degradates were being measured at extremely low levels, studies with possible false positives should not be utilized to support regulatory decisions.
  Science Advisory Panel Issues
  http://www.epa.gov/sites/production/files/2015-06/documents/041012minutes.pdf
  July 11, 2012 "Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting April 10-12, 2012 on "Chlorpyrifos Health Effects."
  Page 12
  SAP - "Also in keeping with the 2008 SAP, this Panel expresses concern about the use of Dimethyl Sulfoxide (DMSO) as a vehicle because of its intrinsic toxicity, its potential influence on absorption and interaction with chlorpyrifos, and the impact of this interaction on the developing organism."
  Page 17 – 18
  SAP – "This is because the studies entail a multichemical exposure spanning a multi-year period that encompasses an important period of sequential developmental processes necessary for brain maturation. Thus, panel members caution that it is very difficult to attribute the independent physiological effects to a single chemical in this type of multi-chemical exposure scenario. An additional concern raised by the Panel is the modest sample sizes of the studies. They deem inadequate sample size as one of the most important limitations of these studies."
  Page 57
  SAP – "For example, in relation to limitations of data on exposure in the epidemiological studies, a Panelist noted that despite a fairly high portion of the samples whose results were below the limit of detection or quantification for whatever was being analyzed, little use was made of techniques to integrate non-quantified samples into the statistical test."

Part B. USDA Comment on the EPA-BEAD "Analysis of the Small Business Impacts of Revoking Chlorpyrifos Food Tolerances"

1. In general, USDA does not agree with the conclusions drawn from the economic analysis provided for the "No SISNOSE" determination. Moreover, EPA's analysis has not been adequately reviewed by USDA. USDA requests that all the data EPA used to support their determination of "no SISNOSE" be available for review by USDA to confirm that EPA has adequately interpreted the agricultural data on pesticide use.

2. EPA-BEAD has arbitrarily set a screening criterion for SISNOSE that is inconsistent with EPA's guidelines. Using EPA's guidance, a "no SISNOSE" is "*not presumed*" if more than 1000 entities are affected by an impact of more than 1%. In addition, EPA's guidance indicates a SISNOSE for a significant effect on more than 1000 entities regardless of the percentage. EPA-BEAD indicates that up to 3500 small entities will have significant impacts (of more than 1%). On page 24 of EPA's own guidance states: "As the number of small entities that will be affected by a rule by more than 1% or 3% of sales or revenues approaches 1000 in number, the substantial number guidelines of 20% of affected small entities may become less relevant in determining whether a regulatory flexibility analysis or a certification should be prepared..." It is unclear why EPA has strayed from that guidance when considering the impact on up to ***3500 small farms (> 1% impact)***.

3. Moreover, EPA seems to have incorrectly used their Table 4.1 to indicate that the number of farms with significant impact is less than 1000 (in table 4.2), when in fact it is approximately 3500. Further, from EPA guidance we see the declaration that "... a rule imposing "significant" economic impacts *on over 1000 small entities is presumed to meet the substantial number threshold*, even if that number represents less than 20% of affected small entities..." (p 27).

4. Therefore, based on EPA's own criterion, this action should be considered at the least "***no presumption***" based on initial screening guidance provided in EPA's 2006 document. Hence, we look to EPA guidance on page 28 to find:

   "...Some analyses that may be helpful in refining an "Uncertain - No Presumption" SISNOSE category are an analysis of cost pass-through, use of or examination of profits or profit margins, measurement of the financial health of entities, or comparing the relative impacts on small entities versus large entities. While the simple initial screen for economic impacts typically assumes that entities are not able to shift some of the burden of higher costs onto consumers, an estimate of cost pass-through can reveal if entities are facing the full burden of the direct compliance costs. When data on profits is available, that information may be used directly, by applying a profit test (see Table 1), or indirectly, by using information on profit margins to inform your selection of appropriate thresholds (see Section 2.6.1) for use with other measures (e.g., cost as a percentage of sales). The financial literature contains many methods of predicting firm (or other entity) health and or closures. Finally, a

comparison of a rule's impact on small entities versus large entities may reveal whether the impacts are disproportionately burdensome to the small entities...."
USDA suggests examining the ability of agricultural producers to pass these costs on to consumers in addition to comparing the cost of compliance on profit margins would better inform EPA's determination.

5. For example, using costs as a % of gross revenues as an economic impact screening test should be accompanied by a % of profits as a screen. http://www.epa.gov/sites/production/files/2015-06/documents/guidance-regflexact.pdf suggests an alternative test for small business SISNOSE as being a "profit test". Using data from USDA, a profit test could be constructed using ARMS data. In a competitive industry, such as agriculture, the use of a profit test would be more reflective of the potential burden on producers from this action. Using that metric USDA suggests EPA would find less support for an indication of "no SISNOSE".

   Again from (EPA, 2006) "...There are several types of information that can help you identify the appropriate threshold values. For example, profits can be a better indicator of ability to pay than sales. Moreover, variation in profit-to-revenue ratios exists across industries. Therefore, the magnitude of impacts defined as the lower and upper threshold for a particular rulemaking may take into consideration the average profit margins of the affected small entities and the ability of the entities to pass compliance costs to either customers or suppliers. To the extent that these types of information are available, you may wish to use them to inform your selection of appropriate thresholds..."

6. Using the percent of acres treated as an indication of impact of revoking use is misrepresentative of the actual benefits to using Chlorpyrifos since the use of the pesticide may be limited to a small section of the field. Without the availability of Chlorpyrifos it may be that many more acres will need to be treated with higher costs. Hence the PCT variable used by EPA to limit the calculation of affected farms is likely an underestimate of the potential compliance burden being imposed by this action.

7. The calculation of compliance costs presumes that the efficacy of the chosen alternatives is equal to Chlorpyrifos. The likely result is a large underestimate of the potential compliance costs associated with this potential action. If that were corrected in the initial screening it is likely that a larger number of crops and farms would have impacts on gross revenue greater than the 1% and 3% thresholds. EPA seems to wave that concern away by indicating that there may be new chemicals under development that may prove to be effective. Of course, that is of little consolation to the small farms that will not be able to adjust to the loss of Chlorpyrifos in the short-run.

Part C. Chlorpyrifos Benefits

Chlorpyrifos is an extremely valuable tool for farmers in managing a wide array of pest insects and is a critical part of Integrated Pest Management (IPM) programs in well over 50 crops grown throughout the United States due to its efficacy, broad-spectrum activity against multiple pests and its fit with conservation biological control in crops, such as citrus, tree fruit and cotton. Revocation of all food tolerances for chlorpyrifos will have a significantly negative impact on the production capabilities and economic stability of producers of many human and animal food crops, particularly where few or no efficacious insecticide alternatives are available, where resistance management with limited alternatives is a concern, where Maximum Residue Limits (MRLs) for effective insecticide alternatives are not established for export markets, and where crops experience invasive and/or endemic pest outbreaks.

Tolerance revocations will have immediate and notable impacts on the economic and production stability of many farm crops. A sampling of crops for which chlorpyrifos use is critical includes cotton ($5.1 billion value of production, USDA-NASS, Crop Values 2014 Summary, February 2015), alfalfa ($10.8 billion, USDA-NASS, Crop Values 2014 Summary, February 2015), non-citrus fruit ($16.3 billion; 2015 USDA Fruit and Tree Nuts Yearbook Tables), citrus ($3.4 billion; 2015 USDA Fruit and Tree Nuts Yearbook Tables), tree nuts ($10 billion; 2015 USDA Fruit and Tree Nuts Yearbook Tables), and vegetables ($13.1 billion; USDA-NASS, Vegetables 2014 Summary, January 2015).

No or few alternative insecticides available:

Cotton: Chlorpyrifos is the only material which has adequate efficacy and plant canopy penetration to prevent defoliation and stunting of cotton seedlings and boll damage from honeydew accumulations due to damage by the cotton aphid (*Aphis gossypii*). Chlorpyrifos is also critical in season-long management of whiteflies (*Bemisia tabaci* Biotype B).

Alfalfa: Chlorpyrifos use in alfalfa is critical when weevils (*Hypera postica* and *Hypera brunneipennis*) and aphids (*Acyrthosiphon kondoi and Acyrthosiphon pisum*) co-occur, with a single application managing both pests. Alternatives are limited and less effective.

Non-Citrus Tree Fruit: The most critical uses of chlorpyrifos for the non-citrus tree fruit industry east of the Mississippi River are for control of tree-boring insects. Management of these pests is required to maintain fruit tree integrity and to prevent severe decline and death of the trees. In assessing economic impact, one must take into account that failure to control borers, due to tolerance revocations making chlorpyrifos unavailable, will result in the loss of all of the trees in a new planting, 100% loss of the cost of the planting, and the income that would have been generated by the orchard block over many years (Dr. Larry Gut, personal communication).

In apple, growers must control the Dogwood Borer, *Synanthedon scitula* (Harris) (Lepidoptera: Sesiidae); American plum borer, *Euzophera semifuneralis (Walker) (Lepidoptera: Pyralidae);* and the ambrosia beetle, specifically the black stem borer (BSB) *(Xylosandrus germanus)* (Coleoptera, Scolytidae). The combined damage of these pests to new high-density apple production on size controlled or dwarfing rootstock, such as the most popular rootstock planted, East Malling 9 (or M.9), has caused severe decline and death of hundreds of trees in the apple

production regions of the Hudson Valley and Western NY. The Black Stem Borer has recently been found to infest newly planted and young apple trees in New York State. Surveys for black stem borer infestations in Michigan apples found that 21 of 24 (88%) young apple plantings surveyed were infested with black stem borer (Dr. Larry Gut, personal communication). Infestations of trees by adult BSB inoculate the tree with a fungal pathogen, with the fungus capable of walling off tree cambium tissue, causing cankers to form leading to tree decline and sudden death in years of drought as we observed in 2015. Presently, chlorpyrifos has shown the greatest level of protection to fruit trees from new infestations from the BSB. Production losses from borer insect pests in apple can exceed 1000 bushels per acre, include replanting costs, with costs of establishment for high-density systems costing around $14,000.00 per acre (Schwallier and Irish-Brown, Michigan State, 2008). Surveys for dogwood borer in Michigan found that a majority (over 50%) of new apple orchards were comprised of trees on rootstocks that are susceptible to dogwood borer and the pest was present. In apple, alternative insecticides for control of tree-boring insects, principally neonicotinoids and pyrethroids, require multiple applications and are far less effective than a single pre-bloom application of chlorpyrifos. Higher populations require chlorpyrifos for effective control.

Tree-boring insects that must be controlled in stone fruit include the American plum borer, the lesser peachtree borer, *Synanthedon pictipes* (Grote and Robinson) (Lepidoptera: Sesiidae) and the peachtree borer, *Synanthedon exitosa* (Grote and Robinson) (Lepidoptera: Sesiidae). The American plum borer causes up to a 33% decline in the life span of tart cherry trees in Michigan. As indicated in the Michigan Fruit Management Guide, a trunk spray of chlorpyrifos, typically applied in June, is the only effective option for control of borers in cherry and peach. There are no alternatives.

Pheromone-mediated mating disruption for several of the borer species in apple is under development, but more research needs to be done to effectively use mating disruption technologies before chlorpyrifos tolerances are revoked. Mating disruption products are registered for use against peachtree and lesser peachtree borer. However, the approach is not effective for preventing borer infestation of cherry and peach, and researchers are unaware of a single Michigan cherry or peach grower that relies on mating disruption for peachtree borer control (Dr. Larry Gut, personal communication).

Citrus: A critical use of chlorpyrifos in citrus is for control of ants that disrupt biological and chemical control of pest aphid, whitefly and scale species that cause direct injury to the plant, and cause further injury through the spread of disease pathogens utilizing the honeydew secretions produced by these pest homopteran species. Chlorpyrifos is the only effective control for ants. Applications target the ground and tree trunk, causing little to no disruption of conservation biological control.

Almond: Critical uses of chlorpyrifos in almond target control of leaffooted bugs (*Leptoglossus zonatus, L. clypealis*, and *L. occidentalis*), stink bugs (*Acrosternum hilare, Chlorochroa uhleri, Thyanta pallidovirens*) and the navel orangeworm (*Amyelois transitella*). Alternative insecticides exist, but are primarily pyrethroids, raising serious concerns with flaring of pestiferous mites and the development of resistance to this one class of insecticides. Chlorpyrifos is also considered critical to the establishment and maintenance of a pheromone mating disruption program for

control of the navel orangeworm by suppressing pest populations to low levels amenable to season-long control with disruption. Navel Orangeworm (NOW) mating disruption is unsuccessful when NOW population pressures are high.

Vegetables: Loss of chlorpyrifos could lead to crop losses for low-acreage, high value brassica crops in Michigan and other states, with few or no alternatives for control. Michigan onion and cabbage growers do have alternatives for control of key pests, but using these would require major changes in equipment and crop production could be lost. Michigan asparagus growers find a single, pre-harvest application is critical for cutworm control, and are willing to relinquish post-harvest applications to maintain this use. Control of cabbage maggot (*Delia radicum*) with chlorpyrifos is critical in turnip, rutabaga and cole crop production. Although limited alternative insecticides are available to use at planting, the application methods for some of these newer insecticides requires the use of different type of planting machinery than what most growers currently have on their farms in Michigan. Michigan onion growers report that loss of chlorpyrifos for control of onion maggot (*Delia antiqua*) would cause challenges to producing onions from transplants and raw seed. Without chlorpyrifos in a heavy pressure year or area, some growers can expect unmarketable onion to be as high as 75%, with a loss of $375,000 in revenue (Dr. Zsofia Szendrei, MSU Entomology, personal communication). Further, some growers produce transplanted onions, securing an early market. Seed treatments cannot be used to protect transplants, and these growers find a single soil application of chlorpyrifos critical for protection against onion maggot. In addition, use of treated seed requires special planting equipment. Loss of chlorpyrifos would require these growers to adjust by obtaining new equipment, and incur the added cost of treated seed (~20% costlier) (Dr. Zsofia Szendrei, MSU Entomology, personal communication).

Resistance management: Chlorpyrifos is one of the last effective organophosphate insecticides available in these cropping systems, providing an important alternative mode of action (MOA) (acetylcholinesterase inhibitor) for rotation with insecticides with differing MOAs in preventing the development of resistance of pest insects to established and newer insecticide products. Rotation of insecticide active ingredient classes from different MOA groups for management of each seasonal insect generation is a foundational tenet for managing insecticide resistance (Insecticide Resistance Action Committee; http://www.irac-online.org/teams/mode-of-action/). The loss of chlorpyrifos will reduce the number of MOA groups available for insecticide rotation, increasing the likelihood for resistance to develop, particularly in endemic insect populations with multiple seasonal generations.

Maximum Residue Limits (MRLs): Chlorpyrifos is a critical pest management tool for producers of commodities with large export markets (*e.g.,* citrus, almonds, apples, cherries, etc.). Many newer insecticides that are deemed as alternatives to chlorpyrifos do not have established MRLs in target markets, impeding trade and resulting in market losses for producers of crops utilizing these alternative materials. The revocation of chlorpyrifos tolerances will result in serious economic hardship for agricultural producers with significant exports to countries where MRLs for alternative materials are not harmonized.

Invasive pests: The occurrence of invasive pests in recent times (*e.g.,* glassy-winged sharpshooter (*homalodisca vitripennis*), brown marmorated stink bug (*Halyomorpha halys*), spotted wing drosophila (*Drosophila suzukii*), Asian citrus psyllid (*Diaphorina citri*) and the black stem borer) in agricultural crops has increased with the expansion of global trade and travel. These pests often increase to damaging levels quickly and may vector disease pathogens, creating emergency situations. Chlorpyrifos is a broad-spectrum material, with well-established MRLs, that can be used to quickly and effectively control invasive pests.

United States Department of Agriculture

Research, Education, and Economics
Agricultural Research Service

April 30, 2015

Richard Keigwin, Director
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs, Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Re: USDA Public Comments on the Chlorpyrifos Registration Review; Revised Human Health Risk Assessment published in the January 14, 2015 Federal Register; EPA docket identification (ID) number EPA-HQ-OPP-2008-0850

Dear Mr. Keigwin:

On behalf of USDA, thank you for the opportunity to comment on EPA's Revised Human Health Risk Assessment for chlorpyrifos published January 14, 2015 in the Federal Register. Chlorpyrifos is an important pest management tool that has been successfully used for over fifty years. USDA appreciates that, in late 2014, EPA further validated the chemical's critical role in U.S. agriculture when chlorpyrifos was listed as one of the alternatives to neonicotinoid seed treatment. (http://www2.epa.gov/sites/production/files/2014-10/documents/benefits_of_neonicotinoid_seed_treatments_to_soybean_production_2.pdf).

However, USDA does have concerns about the risk assessment as it includes potential precedent setting methods for assessing drinking water risk, implementing physiologically-based pharmacokinetic (PBPK) modeling and new methods for deriving the FQPA Safety Factor. The human health assessment could be strengthened by increasing transparency in the discussion of inputs from dietary exposure modeling for the PBPK modeling. It is difficult to identify the use patterns associated with the risk pathways examined. In addition, there is a lack of transparency with regard to the Columbia Study which appears to be the foundation for the FQPA Safety Factor. That study received a critical review by the EPA's Science Advisory Panel in 2012. The criteria for selecting epidemiological studies for use in derivation of safety factors should be provided and reviewed. In this case, without access to the raw data underlying this study it is not possible to fully evaluate the suitability of this study or the degree to which its findings may be generalized for use in a national risk assessment.

USDA's detailed comments are attached. Please let me know if you would like to discuss.

Sincerely,

Sheryl H. Kunickis

Sheryl H. Kunickis, Ph.D.
Director

Office of Pest Management Policy
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USDA Comments on Chlorpyrifos Risk Assessment

The EPA risk assessment on chlorpyrifos represents a substantial amount of effort by the Agency. Given that there are over 82 separate files in the docket associated with the risk assessment, the Agency could better improve communication of the results and identification of the likely risk drivers across the various types of assessments and current use patterns. The Guide to Commenters is helpful but falls short of providing an overall organizational structure for the massive amount of information supporting the risk assessment. We greatly appreciate the transparency EPA has shown in providing the number of supporting documents included in the docket. These documents would better contribute to risk communication if there was a "roadmap" for reading them. It would be useful to have a document linking the primary and supporting material in the docket by category type and date. For example, it would be useful to see a chart comparing all of the use patterns by the estimated risk metric from the human health dietary (food only) assessment, drinking water assessment, residential/bystander assessment, and ecological risk assessment. The chart would include the crops and use patterns (i.e., application rates, timing, etc.) evaluated when feasible. For the dietary assessment, the foods determined to be risk drivers would be included in this chart. Even if the risk metric provided is a qualitative categorical summation of the extremely detailed quantitative estimate, this type of chart would provide very useful information to readers, especially agricultural stakeholder and other users of chlorpyrifos. Within each of the assessments, it would be useful to see the assumptions listed in a tabular form as well as the input data used. Another table providing an estimate of the uncertainty associated with assumptions, specific inputs or model structure would be invaluable.

The risk assessment could be further refined. The aggregate assessment finds exposures from food, residential use and drinking water to be above the levels of concern for some vulnerable population groups. It is unclear which foods may be risk drivers as well as unclear which dermal exposure scenarios in combination with food contribute most to the total exposure. Because the drinking water exposure "fits" into the remaining area of the risk cup after accounting for these other exposure sources, there should be some discussion of the sensitivity of the aggregate model to particular input data used in the dietary and residential assessments. If the residential exposure

is the result of a specific set of assumed scenarios, it would be clearer if the Agency provided sensitivity analysis showing how results might differ if other input data from other scenarios were used. The drinking water risk assessment relies on estimated surface water concentrations – this likely overestimates exposure when community drinking water systems provide water as some of the residue or degradation product will likely be removed due to treatment. Assuming treatment of all possible crop acres where chlorpyrifos is registered could be refined, perhaps using data sets such as the California pesticide use data, to include a more representative typical crop treated scenario. With all of the various assessments, providing estimates of uncertainty about the results would provide additional information.

The derivation of the FQPA factor based solely on epidemiological evidence appears to be a novel application. Previously the FQPA safety factor was supported by laboratory tests required under Part 158. Derivation of the FQPA safety factor has evolved from the initial findings based primarily on the completeness of the toxicity database, the type and severity of the effect observed, and the nature and quality of the available exposure data but the use of epidemiological data has not been well discussed. It would be more transparent if the Agency developed a new standard operating procedure for using epidemiological data when deriving a FQPA safety factor and convened an expert panel to review the SOP. It is not possible to obtain the underlying data for the epidemiological study by the Columbia researchers currently relied upon by the agency. Basing the FQPA safety factor on one or even a small number of epidemiological studies raises reproducibility and reliability concerns. The specific characteristics of the study used that make it reliable, reproducible, generalizability to other populations are not well discussed nor is there a robust discussion of potential sources of uncertainty inherent in the study. Standards for acceptance of such epidemiological studies should be defined. We were unable to locate a standard operating procedure applicable to the use of epidemiological studies when setting the FQPA safety factor, although we did find the 2010 Draft Framework for incorporating Human Epidemiologic & Incident Data in Health Risk Assessment. Among the key guidance documents relied upon by the Agency in the table on page 9 of this Draft Framework is the Food Quality Protection Act 10X Safety Factor document. The use of epidemiological data to support the 10X

factor is not discussed in this document. If epidemiological studies are to form the basis of the FQPA factor, a new standard operating is needed.

Unless the risk mitigation actions are to be conducted on a watershed basis, using a watershed or community water system as the geographic scale for the drinking water risk estimation is likely to mischaracterize the risk when considered at a national or regional scale. The Agency asks for comments on this new capability for targeting – further information on the potential use of this information in risk characterization and potentially risk mitigation is needed.

These types of watershed analyses should also include monitoring data or other empirical measurements of chlorpyrifos to provide some evaluation of the ability of the modeling approaches used to simulate actual observed in-stream concentrations. There are many types of uncertainties inherent in watershed simulation. Verification that the modeling approach is reliably able to simulate the behavior of chlorpyrifos concentrations in lotic or lentic environments would increase confidence in the drinking water exposure assessment. Further analysis of monitoring data from finished drinking water samples from community water systems would provide real-world data on actual exposures. More explanation is needed for the Agency's drinking water intake database for identification of vulnerable community water systems. The assumption that a portion of the watershed is treated will influence the estimation of chlorpyrifos concentrations in surface water. This will be difficult to determine in States other than California where pesticide usage is recorded by crop for individual users. Assuming all registered use patterns undergo treatment during the same year or season will overestimate exposure.

EPA Should Reduce the 10X FQPA Safety Factor

USDA encourages EPA to reconsider the retention of the default 10X FQPA safety factor for infants, children, youths, and women of childbearing age, which had been reduced to 1X for most exposure routes in the 2011 Preliminary Human Health Assessment. The primary purpose of the FQPA safety factor is to address inadequacies or gaps in required studies or when important data needed to evaluate risks to children are missing or inadequate ("Determination of the Appropriate FQPA

Safety Factor(s) in Tolerance Assessment," Office of Pesticide Programs, U.S. Environmental Protection Agency, Feb. 28, 2002). USDA believes that no significant data deficiencies exist in this case, and that therefore EPA should not be precluded from reducing the 10X FQPA safety factor.

The points of departure in this assessment are derived from PBPK-PD modeling and are modified by data-derived extrapolation factors (DDEF), as opposed to a traditional approach encompassing a NOAEL and uncertainty factors. EPA's ability to use PBPK-PD modeling and DDEF demonstrates how comparatively data-rich its situation is when addressing chlorpyrifos. As a result of the many years of thorough study and evaluation of chlorpyrifos, it is inappropriate to use the default 10X FQPA safety factor which is intended for assessments with significant data deficiencies.

The purpose of the FQPA safety factor is to account for uncertainties present in the relationship between an adverse outcome observed in research studies (usually quantified in a point of departure) and a *corresponding* acceptable human exposure level (such as a population adjusted dose). In this assessment, EPA is evaluating two separate adverse outcomes: 10 % inhibition of RBC AChE and the neurodevelopmental effects potentially detected by the Columbia Study. The 10X FQPA safety factor is ostensibly *justified* due to uncertainty associated with the neurodevelopmental effects, but it is then *applied* to the point of departure based on 10 % inhibition of RBC AChE. This point of departure is based on extensive data and research, and does not contain any of the uncertainties that would usually require an FQPA safety factor greater than 1X.

If EPA could substantiate the connection between exposure to chlorpyrifos and the neurodevelopmental effects observed in the Columbia Study and could calculate a point of departure for these adverse outcomes, it might be appropriate to apply uncertainty and safety factors to this new neurodevelopmental point of departure. However, the limitations of the epidemiologic studies, which do not provide a clear understanding of exposure, dose-response, or mode of action/adverse outcome pathway, do not allow such a point of departure to be

calculated. These same, limited epidemiologic studies should not be used to justify the addition of an FQPA safety factor to the much more robust 10 % inhibition of RBC AChE point of departure.

Epidemiological Issues

USDA agrees with the concern raised by some SAP members in 2012 regarding the potential neurodevelopmental effect of chlorpyrifos based on the Columbia cohort. Exposure to other chemicals other than chlorpyrifos may have influenced the outcome. The Panel suggested that, given the short half-life of chlorpyrifos, a longitudinal study with frequent measurements throughout pregnancy would "fill many of the data gaps." A well-designed study would overcome "inadequate sample size" limitations.

USDA urges that the data be made available to the broader toxicology community for quality review given that the SAP "expresses concern over the Agency's focus on a 10% AChE (acetyl cholinesterase) activity reduction." The Panel worried that "there is no proposed mechanism whereby a 10% AChE activity reduction would be responsible for a cognitive defect or developmental delay in their offspring."

http://www.epa.gov/scipoly/sap/meetings/2012/april/041012minutes.pdf,

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"Although in agreement with the Agency that chlorpyrifos could have played a role in the neurodevelopmental outcomes observed in the Columbia cohort, some panel members expressed concern about associating the observed deficits in neurodevelopmental outcomes in children with a single chemical. This is because the studies entail a multichemical exposure spanning a multi-year period that encompasses an important period of sequential developmental processes necessary for brain maturation. Thus, panel members caution that it is very difficult to attribute the independent physiological effects to a single chemical in this type of multi-chemical exposure

scenario. An additional concern raised by the Panel is the modest sample sizes of the studies. They deem inadequate sample size as one of the most important limitations of these studies."

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"The Panel notes that it is important to realize that the short half-life of chlorpyrifos and its metabolites in the body calls into question any "spot data" that might be used. Large cross-sectional studies may capture some exposure but they do not put these exposures into context. Longitudinal investigations with frequent samplings are more likely to provide data that are more useful. Thus, the Panel recommends that a longitudinal study with measurement throughout the pregnancy (rather than a few samples in the last trimester) would fill many of the data gaps that currently exist for this group. Such a study is needed given the potential for neurodevelopmental effects on the fetus as well as the metabolic differences in pregnant women versus the workers from the 1984 study."

"Lastly, the Panel expresses concern over the Agency's focus on a 10% AChE activity reduction. They point out that to their knowledge there is no proposed mechanism whereby a 10% AChE activity reduction in pregnant women would be responsible for a cognitive defect or developmental delay in their offspring."

Occupational Risk Assessment

USDA notes that the use of a 10X safety factor employed in the chlorpyrifos risk assessment as a result of the Columbia University cohort was incorporated into the occupational assessment for chlorpyrifos. USDA considers that the application of a default FQPA10X safety factor for women of child-bearing age for workers is beyond the scope of the requirements of the Food Quality Protection Act. During the Registration Review effort, EPA had appropriately adhered to the FQPA requirements by combining exposures from only dietary, residential, and drinking water sources.

In keeping with the recommendation of the 2012 SAP, USDA urges that EPA call-in data from the registrant for improving the endpoints of the chlorpyrifos occupational risk assessment. PBPK

modeling might be used to determine an appropriate intraspecies uncertainty factor specific for chlorpyrifos for women in pregnancy.

http://www.epa.gov/pesticides/regulating/laws/fqpa/fqpa_implementation.htm

" FQPA requires EPA to consider all "aggregate risk" from exposure to a pesticide from multiple sources when assessing tolerances."

"EPA has developed sound scientific procedures for evaluating aggregate exposures to pesticides. These new and improved procedures have enabled EPA to conduct risk assessments that combine exposures from dietary, residential, and drinking water sources, and to ensure that exposure to pesticides in food are safe in light of the aggregate exposure."

Critical need for chlorpyrifos

Chlorpyrifos is a broad-spectrum control material that has been a part of growers' IPM programs for about 50 years to control a wide array of primary and secondary pests in over 75 cropping systems. The impacts to these cropping systems if chlorpyrifos was eliminated or severely restricted would be immediate and deeply experienced, in terms of efficacy of pest management programs, increased costs to growers switching to more expensive, more frequently applied and less effective alternatives, and disruption to current and historical IPM programs across these cropping systems. In some systems a lack of effective alternatives targeting control of primary pests, such as root maggot in sugar beets, presents serious concern of economic damage if the pest is left uncontrolled.

Crop uses: Major Crops: Soybean, corn (field, sweet and seed), cotton, wheat, sorghum, sugar beet, sunflower, tobacco, and almond.

Minor Crop Uses (chlorpyrifos use in minor crops is applied predominantly with the use of ground application technologies (ground booms and airblast), with some aerial applications made in walnut): apples, grape, stonefruit (5 crops), pears, alfalfa, fig, strawberry, cole crops (18 crops), legume vegetables (over 3 dozen),

cucumber, ginseng, citrus (15 crops), cranberry, mint, onion, peanuts, sunflower, sweet potatoes, walnuts, filberts, pecans, asparagus, brussel sprouts, cranberries, broccoli, and cauliflower.

Non-crop uses: Golf courses, turf (sod), green houses, Christmas trees, non-structural wood treatments such as utility poles and fence posts, ant bait stations, fire ant control and mosquitoes, clover for seed, and ornamental trees (nursery).

In addition to its efficacious broad-spectrum control, growers have a historical knowledge of how chlorpyrifos fits into a season-long control program to manage an array of pests. For example, use of chlorpyrifos in tree fruit and tree nut crops is timed to target control of pest insects with minimum harm to beneficial natural enemies of mites, aphids and scale insects, thereby maximizing control of these secondary pests through conservation biocontrol. Many of the alternatives to chlorpyrifos, primarily pyrethroid insecticides, are lethal to beneficial natural enemies, thereby requiring additional spray applications to control secondary pests.

Chlorpyrifos is also an important tool for growers in addressing consumer and regulatory demands for zero tolerance for insect infested fruit at harvest. Alternatives to chlorpyrifos present an array of challenges to producers, including meeting Maximum Residue Limits (MRL) for sale of food and fiber to export markets and management of invasive pest species, such as the brown marmorated stinkbug.

Chlorpyrifos currently has many use restrictions to mitigate risk in a number of cropping systems to workers and the environment. Use for in-season application in grapes is not allowed (no application to fruit or foliage), is limited to one dormant/delayed application in stone and pome fruit (a post-bloom application to the lower four feet of apple tree trunks to protect against tree-boring insects), has a 24-hour use restriction in conjunction with flood irrigation to avoid contamination of tail waters, and an array of Pre-Harvest Intervals (21 day PHI in peanut, 60 days in onion, 90 days in mint and 125 day PHI in sweet potato), to manage residue on food and protect

workers. Use is currently restricted to one application per year in apple (either pre-bloom dormant or post-bloom tree trunk), cranberry, legume vegetables (except soybean), onion, peanut (pre-plant), pear (post-harvest), mint, strawberry, sweet potato, tobacco, almond (no application on almonds in the following counties in California: Butte, Colusa, Glenn, Solano, Sutter, Tehama, Yolo, and Yuba) walnut, nectarine, and peach.