



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0653; FRL-9954-65]

Chlorpyrifos; Tolerance Revocations; Notice of Data Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule

SUMMARY: EPA is announcing and inviting comment on additional information obtained and developed by EPA in conjunction with the proposed tolerance revocation for chlorpyrifos. This information includes the revised human health risk assessment and the drinking water assessment. It also includes EPA's issue paper and supporting analyses presented to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Scientific Advisory Panel's (SAP) meeting in April 2016 that addressed chlorpyrifos biomonitoring data and adverse neurodevelopmental outcomes, public comments received during the meeting, the FIFRA SAP's meeting minutes and the FIFRA SAP report. EPA is specifically soliciting comments on the validity and propriety of the use of all the new information, data, and analyses. EPA is accepting comment on the information and analysis, as well as reopening comment on any other aspect of the proposal or the underlying support documents that were previously available for comment. The EPA continues to seek comment on possible mitigation strategies, namely, use deletions, which might allow the EPA to retain a small subset of existing chlorpyrifos food uses. Commenters need not resubmit comments previously submitted. EPA will consider those

comments, as well as comments in response to this notice, in taking a final action.

DATES: Submit comments on or before [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2015-0653, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Dana Friedman, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW, Washington, DC 20460-0001; telephone number: (703) 347-8827; email address: friedman.dana@epa.gov.

SUPPLEMENTARY INFORMATION:

I. How Should I Submit Confidential Business Information (CBI) to the Agency?

Do not submit this information to EPA electronically. Clearly mark the part or all of

the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

II. Purpose of this Document

EPA is reopening the comment period on the proposed rule: entitled “Chlorpyrifos; Tolerance Revocations” (80 FR 69080, November 6, 2015) (FRL-9935-92), herein referred to as the “proposed rule,” for the purpose of obtaining public comment on the additional information and analyses announced in this document and which may be relevant to the development of a final action. EPA is also accepting comment on any other aspect of the proposal or the underlying support documents that were previously available for comment. As explained in the proposed rule, the timing of EPA’s issuance of the proposal was dictated by an August 10, 2015 order by the U.S. Court of Appeals for the Ninth Circuit in *Pesticide Action Network North America (PANNA) v. EPA*, No. 14-72794. The *PANNA* decision directed EPA to respond by October 31, 2015 to PANNA and the Natural Resource Defense Council’s (NRDC) petition to revoke all chlorpyrifos tolerances and cancel all chlorpyrifos registrations. As a result of that timing, EPA had not yet completed portions of its scientific assessment when it issued the proposed rule. Specifically, EPA noted that it issued the proposed rule in advance of completing a refined drinking water assessment and without conducting additional analysis of the hazard from chlorpyrifos in response to comments

received on EPA's December 2014 Revised Human Health Risk Assessment. Accordingly, EPA noted in the proposed rule that it would update the proposal with any new or modified analyses, as EPA completed additional work after the proposal and, to the extent practicable, EPA would provide the public an opportunity to comment on that work prior to issuing a final rule. Consistent with that commitment, EPA is today seeking comment on the following documents that were not available for public comment during the prior comment period on the proposed rule: *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review (2016)*; the materials and final report from the 2016 Chlorpyrifos SAP; and *Chlorpyrifos Registration Review Drinking Water Assessment*.

EPA's revised analyses do not result in a change to the EPA's proposal to revoke all tolerances but it does modify the methods and risk assessment used to support that finding in accordance with the advice of the SAP. The revised analysis indicates that expected residues of chlorpyrifos on most individual food crops exceed the "reasonable certainty of no harm" safety standard under the Federal Food, Drug, and Cosmetic Act (FFDCA). In addition, the majority of estimated drinking water exposures from currently registered uses, including water exposures from non-food uses, continue to exceed safe levels even taking into account more refined drinking water exposures. Accordingly, based on current labeled uses, the agency's analysis provided in this notice continues to indicate that the risk from the potential aggregate exposure does not meet the FFDCA safety standard. EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe. EPA has not identified a set of currently registered uses that meets the FFDCA safety standard because it is likely only a limited number of food uses alone, and in combination with predicted drinking water exposures, would meet the standard. Further, EPA has not received any

proposals for mitigation that registrants may be willing to undertake that would allow the EPA to retain any of the tolerances subject to this rulemaking. EPA continues to seek comment on possible mitigation strategies, namely, use deletions, which might allow the EPA to retain a small subset of existing chlorpyrifos food uses.

EPA consulted the FIFRA SAP for scientific advice on its analysis of biomonitoring data at a meeting on April 19 - 21, 2016, at which time, the public also had an opportunity to provide comment. The FIFRA SAP was asked to address the use of the epidemiological study *The Mothers and Newborn Study of North Manhattan and South Bronx* performed by the Columbia Children's Center for Environmental Health (CCCEH) at Columbia University to establish a new toxicological endpoint and associated point of departure for chlorpyrifos based on observed adverse neurodevelopmental outcomes in children resulting from prenatal exposure to chlorpyrifos. While the residential uses that resulted in chlorpyrifos exposures in the CCCEH study were cancelled in 2000, EPA believes this study remains relevant in evaluating risks from exposure to currently registered uses. In its presentation to the SAP, EPA proposed to use biomonitoring data (cord blood concentrations) identified in the CCCEH study (Rauh *et al*, 2006 and Rauh *et al*, 2011) as the basis for its point of departure. The FIFRA SAP provided feedback indicating that it did not believe using the cord blood data from that study was appropriate to establish a new point of departure. The SAP's primary criticism was that there was not enough data on the relationship between cord blood concentrations at birth to exposures at and around the time of chlorpyrifos application to support its use in quantitative risk assessment. Further, the FIFRA SAP noted that EPA's assessment did not identify a particular window of exposure within the prenatal period linked to the effects reported. Generally, however, the FIFRA SAP agreed with the overall

conclusion of the CCCEH study, i.e. the association between prenatal chlorpyrifos exposure and neurodevelopmental outcomes in children.

The final FIFRA SAP report provides a detailed account of the uncertainties associated with the agency's April 2016 proposed approach to selecting the point of departure and its use in quantitative risk assessment. It also outlines the SAP's concern that "epidemiology and toxicology studies suggest there is evidence for adverse health outcomes associated with chlorpyrifos exposures below levels that result in 10% red blood cell (RBC) acetylcholinesterase (AChE) inhibition" (FIFRA SAP, 2016, p. 18). The FIFRA SAP recommended that EPA should derive the point of departure for neurodevelopmental effects using the "estimated peak blood concentration or time weighted average blood concentration within the prenatal period" (FIFRA SAP, 2016, p. 42).

After careful consideration of public comments and the SAP's recommendations, EPA has concluded the most appropriate path for reconciling the SAP's concerns is to follow through on the SAP's recommendation to use a time weighted average approach. The agency agrees with the 2016 FIFRA SAP (and previous SAPs) that there is a potential for neurodevelopmental effects associated with chlorpyrifos exposure to occur at levels below 10% RBC AChE inhibition, and that EPA's existing point of departure (which is based on 10% AChE inhibition), is therefore not sufficiently health protective.

As detailed in *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review (2016)*, in order to follow up on the SAP's recommendation that the point of departure should be based on blood concentrations at the time of exposure to chlorpyrifos (rather than based on cord blood at the time of delivery), EPA evaluated the most likely chlorpyrifos application method to determine peak exposures to the CCCEH study cohort

experiencing neurodevelopmental effects in children. EPA contacted the technical pest advisor responsible for overseeing New York City's housing authority in order to confirm the application method used at the time the CCCEH study was conducted. Based on those conversations and a review of the registered uses available during that period, EPA concluded that crack and crevice treatments were the most likely exposure pattern among those use patterns registered at the time of the study and therefore has used these exposures as the basis for a new point of departure.

EPA generally selects the dose at which no toxicological effects are demonstrated to ensure our regulatory endpoint reflects a level of exposure that does not present a risk concern. However, the CCCEH study only supported the determination of a lowest observed adverse effects level (LOAEL). In situations where the agency selects a POD from a study where a no observed adverse effects level (NOAEL) has not been identified, EPA generally will retain the Food Quality Protection Act (FQPA) safety factor of 10X to account for the uncertainty in using a LOAEL. The 2016 revised risk assessment retains this uncertainty factor for chlorpyrifos and also applies a 10X uncertainty factor for intraspecies variability because of the lack of sufficient information to reduce or remove this factor.

The external exposure was calculated based on the assumptions and methods outlined in the EPA's 2012 Standard Operating Procedures (SOPs) for Residential Pesticide Exposure Assessment and chemical-specific exposure data, where available. Specifically, the 2012 Residential SOPs, which were peer reviewed by the FIFRA SAP in October 2009, were used to predict the potential exposures which could have occurred to individuals in the cohort for the indoor crack and crevice pesticide use pattern.

EPA then used the chlorpyrifos physiologically based pharmacokinetic (PBPK)

model to estimate the study cohort mothers' systemic dose related to the LOAEL by (1) determining time-weighted average (TWA) blood levels from women exposed to chlorpyrifos from indoor exposures to the cancelled crack and crevice use and (2) using the crack and crevice TWA blood level as the internal dose for determining points of departure for infants, children, and adults exposed to chlorpyrifos using current exposure potential. The use of the PBPK model to assess internal dosimetry from various exposure scenarios continues to be supported by the SAP. This applies to the crack and crevice scenario identified as the most likely exposure pattern in the CCCEH study, where women were potential exposed via the dermal, oral, and inhalation routes. The detailed rationale is presented in *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review (2016)*.

EPA has also completed, and is making available for public comment, *Chlorpyrifos Registration Review Drinking Water Assessment*. EPA conducted a national screening level drinking water assessment in 2014. Because of the court decision ordering EPA to respond to the PANNA-NRDC Petition by October 31, 2015, EPA was not able to complete a more refined drinking water assessment for chlorpyrifos in advance of the proposed rule. Since that time EPA conducted the refined drinking water assessment with the intention of providing a basis for supporting a more tailored approach to risk mitigation. In the proposal, EPA proposed revoking all tolerances largely because the agency could not make a safety finding based on drinking water exposure in highly-vulnerable watersheds. EPA reasoned if it could better identify where such vulnerable areas might be, it could be possible for registrants to amend product labeling in ways that might make unnecessary some number of the proposed tolerance revocations.

Chlorpyrifos Registration Review Drinking Water Assessment serves to combine, update and complete the work presented in the 2011 and 2014 drinking water assessments for chlorpyrifos as part of the registration review process. This document specifically focuses on the exposure estimates for surface water. The 2014 assessment presented an approach for deriving more regionally-specific estimated drinking water exposure concentrations for chlorpyrifos and chlorpyrifos- oxon for two water resource regions, hydrologic unit code (HUC) - 02. This assessment updates those exposure assessments and provides estimates for the remaining (i.e., 19) HUC- 02 regions. Urban uses, which had not previously been assessed, are included in this update. This assessment also includes statistical analysis of all available monitoring data for chlorpyrifos and chlorpyrifos- oxon. While this drinking water assessment is more refined than the previous assessments, as a general matter, the results did not allow for identification of many areas where potential exposures of concern to drinking water can be ruled out. As a result, this assessment does not significantly alter the conclusions in the proposed rule regarding drinking water exposure and continues to indicate potential exposure to chlorpyrifos or chlorpyrifos- oxon in finished drinking water across the country based on currently labeled uses. This is supported by both model estimated concentrations as well as measured chlorpyrifos concentrations in surface water across the United States.

Section IV of this Notice of Data Availability (NODA) describes all additional data and analyses and how they impact the EPA's proposal. Note, however, that this NODA does not provide an exhaustive presentation of the additional data and analysis that EPA is placing in the associated docket and seeking comment on. All the information subject to this notice can be accessed as described in section III of this notice.

EPA is providing notice on these additional analyses to provide an opportunity for the public to submit additional data or information for the agency's consideration as it develops the final rule. Since EPA is still in the process of deliberating the provisions of a final rule, EPA cannot definitively state whether this information will provide support for any provision of the final rule, or that the agency has determined that it is appropriate to rely on this information in developing the final rule.

On December 10, 2015, the Ninth Circuit issued a further order requiring EPA to complete any final rule and fully respond to the PANNA and NRDC petition by December 30, 2016. On June 30, 2016, EPA sought a 6-month extension to that deadline in light of the SAP's recommendation at the meeting and in order to allow EPA to fully consider the SAP's written report. The FIFRA SAP report was finalized and made available for EPA consideration on July 20, 2016. The court rejected EPA's request for a 6-month extension and ordered EPA to complete its final action by March 31, 2017 (an extension of 3 months). The court also announced that no further extensions to that date would be granted.

III. Where Can the Information Identified in this Document be Found?

The information that EPA is be made available for public review and comment can be found in the following dockets: EPA-HQ-OPP-2015-0653, the docket for the proposed tolerance revocations, and EPA-HQ-OPP-2016-0062, the FIFRA SAP docket, which contains the Chlorpyrifos Issue Paper and supporting materials. Both dockets can be accessed through <http://www.regulations.gov>. As noted, EPA is also reopening the comment period to allow for comment on any aspect of the proposed revocation published on November 6, 2015 (80 FR 69080) (FRL-9935-92).

IV. What Analysis and Data are Being Noticed?

1. EPA is seeking comment on the following updates to the chlorpyrifos human health risk assessment: (1) use of the crack and crevice scenario to derive an exposure level for women in the Columbia study; (2) using the LOAEL from the Columbia study and PBPK modeling to derive an endpoint for use in quantitative risk assessment; (3) use of the 10X uncertainty factor for intraspecies variability; (4) use of the 10X FQPA safety factor for LOAEL to NOAEL extrapolation (please include your rationale for any alternative values suggested for this factor). Its analysis is included in the *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review (2016)*, which is available in the chlorpyrifos tolerance revocation docket (EPA-HQ-OPP-2015-0653).

2. EPA is also making available for comment the issue paper and associated materials presented to the April 2016 FIFRA SAP and the final report of the SAP. The FIFRA SAP materials and final report are available in the FIFRA SAP docket (EPA-HQ-OPP-2016-0062).

3. EPA is also seeking comment on *Chlorpyrifos Registration Review Drinking Water Assessment*, a highly refined drinking water assessment that updates and completes the agency's examination of exposure through drinking water for all registered uses of chlorpyrifos. This assessment integrates regionally specific (*i.e.*, spatially relevant) estimated drinking water concentrations and an extensive evaluation of available surface water monitoring data for chlorpyrifos and chlorpyrifos-oxon. The assessment considers both agricultural and non-agricultural uses of chlorpyrifos, a sensitivity analysis for model estimated concentrations, and statistical evaluation of surface water monitoring data.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 10, 2016.

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Acting Director, Office of Pesticide Programs.

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