UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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Dear Ms. Bladow and Mr. Markwart:

Thank you for your letter of September 7, 2021, to the U.S. Environmental Protection Agency (EPA) regarding chlorpyrifos. Below are the questions that you posed to the Agency and the Agency's responses to those questions. At the end of this response, we have also provided the questions sent on September 9, via email, from Scott Herndon, the Vice President and General Counsel of the American Sugarbeet Growers Association, and the Agency's responses to those questions.

Historical Categorization/Technical Correction:

1) Could you help us understand the process and timing surrounding the upcoming chlorpyrifos cancellation order, guidance and Q&A?

Agency Response: Q&A were available on EPA's website at: [HYPERLINK "https://www.epa.gov/ingredients-used-pesticide-products/frequent-questions-about-chlorpyrifos-2021-final-rule"] *beginning on September 20, 2021.*

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of the final rule and may also request a hearing on those objections. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 29, 2021. Please see Section I.C of the final rule for instructions on providing feedback. EPA will review any objections and hearing requests in accordance with 40 CFR 178.30, and will publish its determination with respect to each in the Federal Register.

Any registrant, including those who hold registrations of chlorpyrifos, can cancel the registration of a pesticide product or use at any time by voluntarily submitting a request to the Agency. If no requests are submitted, the Agency can issue a Notice of Intent to Cancel (NOIC) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to cancel registered food uses of chlorpyrifos associated with the revoked tolerances. When EPA issues an NOIC, it will be published in the Federal Register. For more information on the NOIC process, visit EPA's website: [HYPERLINK "https://www.epa.gov/pesticide-tolerances/pesticide-cancellation-under-epas-own-initiative"].

(continuation of question #1): The final rule that was published in the Federal Register on 8/30/21 states, "In this final rule, EPA is revoking all tolerances for chlorpyrifos contained in 40 CFR 180.341." However, in EPA's 8/18/21 stakeholder briefing and in press reports, EPA indicated some uses will remain (namely for cotton, cow tags and golf courses). How will these and other commodities be able to retain uses?

Specifically:

a. Will any tolerances contained in 40 CFR 180.342, other than cotton, be preserved outside of the 8/18 announced final rule, and then potentially undergo reregistration in the final Interim Decision for Chlorpyrifos, which is statutorily required in 2022? Will EPA consider data that may allow other commodities to be considered in this process to retain uses?

b. If not, will cotton and other uses set to be preserved, be revoked, and then potentially reregistered through either: 1) a new registration process; or 2) an alternative means of registration RUP and/or Sec. 18 Emergency Exemption under FIFRA?

Agency Response: During the stakeholder meeting, we did state that the final rule does not impact non-food uses of chlorpyrifos. The Agency referenced cattle ear tags, public health uses for mosquito control, and USDA quarantine use for fire ant control. However, ear tags should not have been included in this list. Use on cattle ear tags is considered a food use because residues have been detected in cattle milk and fat, which are considered human food and/or animal feed. In addition, use on commodities such as cotton is considered a food use because products derived from it are considered human food and animal feed; therefore, tolerances are required. Application after the tolerances expire would render these products to be adulterated, and distribution in interstate commerce would be a violation of the FFDCA. Products in the channels of trade that contain chlorpyrifos residues and were treated prior to the expiration of the tolerances would be governed by section 408(l)(5) of the FFDCA, which describes conditions that must be met in order for such food to be distributed. EPA has been working closely with FDA on guidance for treated commodities in the channels of trade that is expected to be published by the date the tolerances expire on February 28, 2022.

Per the Revised Human Health Risk Assessment for Registration Review, residential post-application exposures can occur for adults and children golfing on chlorpyrifos-treated golf course turf and from contacting treated turf following a mosquitocide application. There are no residential post-application risk estimates of concern for adults or children from chlorpyrifos use on golf course turf or as a mosquitocide on the day of application. EPA will continue to evaluate the non-agricultural, non-food uses as part of the ongoing registration review for chlorpyrifos, which is expected to be completed by October 2022.

2) Should sugar beets have originally been considered "non-food uses," given our data demonstrates zero residues on our end food and feed products and FDA studies from 2002-2017 (most recent) demonstrate no chlorpyrifos residues on sugar?

a. Could you provide us with an initial understanding of why EPA has set the tolerances for sugar beets as "food-uses" in 40 CFR § 180.342 and in the updated 2020 Proposed Interim Registration Review (PID)?

b. Should sugar beets originally have been considered "non-food uses" under 40 CFR § 180.2003 (Subpart E – Pesticide Chemicals Not Requiring a Tolerance or an Exemption From a Tolerance) which is defined as:

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"(b) Non-food uses are those uses that are not likely to yield residues in food or feed crops, meat, milk, poultry or egg." Our data confirms there are no residues in our end products (see below information on lack of residues on sugar beets)."

Furthermore, the most recently published FDA Total Diet Studies from 2014-2017 tested sugar for traces of chlorpyrifos and found none.

c. The Pesticide Residue Monitoring Program Fiscal Year 2016 Pesticide Report examined residues in food and feeds and did not mention any findings of residues of chlorpyrifos in food or animal foods. Can EPA explain why they believe that residues for chlorpyrifos exist on sugarbeet products?

Agency Response: The sugar beet use of chlorpyrifos is and should be considered a food use. In addition to the residues in sugar beet roots (1 ppm tolerance), residues concentrate in the processed commodities of molasses (15 ppm tolerance) and dried pulp (5 ppm tolerance), both of which are livestock feedstuffs and may contribute to residues in meat and milk. Also, Codex established an MRL for sugar beets at 0.05 ppm for chlorpyrifos. Since we established tolerances previously with the available data, any reconsideration of status as a food use would have to come in through the PRIA process.

d. Is EPA aware our data demonstrates no residues on our end products such as crystallized sugar, molasses, dried pulp? As you may know, sugar beet co-ops do significant testing on our products for quality control. Our data indicates zero chlorpyrifos residues remain on our end products sold into commerce—which are crystallized sugar, dried pulp, and molasses. This contradicts the definition of "food-uses," which are defined as:
"(a) food uses are the uses of a pesticide chemical that are likely to yield residues in food or feed crops, meat, milk, poultry or egg."
What is the best way to provide you our data to update your analysis?

Agency Response: The study numbers (MRIDs) would need to be provided to confirm whether the Agency has these data or not; however, these data will likely not change our conclusions since they appear to be monitoring data rather than field trial data which are used to set tolerances. Tolerances are established based on residues "at the farm gate". Monitoring data could be collected at any point in the chain of commerce and would likely not be acceptable for establishing tolerances or determining food-use status. Since the Agency established tolerances previously with the available data, any reconsideration of status as a food use would have to come in through the PRIA process.

3) Could you provide us with an understanding of how EPA has set the tolerances for sugar beets in 40 CFR § 180.342 and in the updated 2020 Proposed Interim Registration Review (PID)? Both are mentioned in your final rule.

Agency Response: Field trial data are used to set tolerances. Tolerances are established based on residues "at the farm gate". For more information about how we set tolerances, please see the following link: [HYPERLINK "https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods" \l "food-safety"]. *Tolerances are set on the processed commodities of sugar beets based on processing studies. For more information describing all of the processed commodities from sugar beets which we consider (e.g., molasses), please see the following link:* [HYPERLINK "https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0155-0002"].

a. When considering dietary risk, does the data factor in that sugar beets are not consumed raw nor are they sold into interstate commerce to be consumed raw? In fact, the user agreement that growers

must sign to utilize the seed technology, states that the grower agrees that sugarbeet seeds, and the resulting crop, are solely for the processed sugar, energy production, or animal feed.

Agency Response: Use on commodities such as sugar beet is considered a food use because products derived from it are considered human food and animal feed; therefore, tolerances are required. For sugar beets (consumed as the processed blended commodities sugar and molasses), a processing factor of 0.02 was applied to the sugar beet (Raw Agricultural Commodity (RAC)) tolerance of 1 ppm and corrected for 20% crop treated to come up with a residue of 0.004 ppm. For more information about how we set tolerances, please see the following link: [HYPERLINK "https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods" \l "food-safety"]. *For more information describing all of the processed commodities from sugar beets which we consider (e.g., molasses), please see the following link:* [HYPERLINK "https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0155-0002"].

b. Chlorpyrifos is a contact insecticide that is not absorbed by or translocated within a plant which would explain the lack of residue in sugar beet and its related products.

c. Similar to EPA's PDP, a US Market Basket Analysis found 90% of all products tested were absent of chlorpyrifos and the remaining 10% well below legal tolerances.

d. Although Eaton et al. recognize consumptive exposure as the greatest non-occupational exposure they concluded: "Based on the weight of the scientific evidence, it is highly unlikely that current levels of chlorpyrifos exposure in the United States would have any adverse neurodevelopmental effects in infants exposed in utero to chlorpyrifos through the diet." These authors applied extensive scientific rigor in comparing studies from Columbia, Mount Sanai, and Berkley. Although two showed correlative effects between chlorpyrifos levels there was zero consistency between cohorts when analyzed by meta-analysis suggesting no causal relationship between chlorpyrifos levels and neurological issues. The authors concluded up to 10 ppb per day of exposure resulted in no adverse effects.

e. Given the aspects in points why would there need to be a tolerance for tops, and leaves for food or feed? Page 50 of the final rule states: "EPA has determined that the metabolite chlorpyrifos oxon is not a residue of concern in food or feed, based on available field trial data and metabolism studies that indicate that the oxon is not present in the edible portions of the crops. In addition, the chlorpyrifos oxon is not found on samples in the USDA PDP monitoring data. Furthermore, the oxon metabolite was not found in milk or livestock tissues"

Agency Response: There are chlorpyrifos residues found in sugar beet tops as indicated by the established tolerances. The fact that residues of the metabolite, chlorpyrifos-oxon, are not present does not change the conclusion that tolerances for these commodities are required.

4) Where did EPA's existing residue data for sugar beet originate? As noted in your rule, "Both the acute and steady state dietary exposure analyses are highly refined. The large majority of food residues used were based upon PDP monitoring data except in a few instances where no appropriate PDP data were available. In those cases, field trial data or tolerance level residues were assumed." The PDP data base does not list sugar or sugar beets as a commodity.

a. Given this omission, and given that our data shows no residues, is the field data being used to determine residue, despite the fact that no raw sugar beet enter commerce for human consumption?

b. If EPA retains such field data, can we work with the agency to retroactively correct it so that the agency's science is more accurate?

Agency Response: For sugar beets (consumed as the processed blended commodities sugar and molasses), a processing factor of 0.02 was applied to the sugar beet (Raw Agricultural Commodity (RAC)) tolerance of 1 ppm and corrected for 20% crop treated to come up with a residue of 0.004 ppm.

As a reminder, chlorpyrifos risks from food, including sugar from sugar beets and all other foods, is very low and not of concern; sugar beets are not expected to contribute significant risk to the total dietary exposure. The primary contribution to overall chlorpyrifos risks is from residues in drinking water. In setting tolerances, EPA must consider aggregate exposure, which consists of food, drinking water, and any residential exposure. Regardless, use on sugar beets remains a food use requiring tolerances. Since the Agency established tolerances previously with the available field trial data, any reconsideration of status as a food use would have to come in through the PRIA process. Additionally, field trial data are used to establish tolerance levels reflective of residues likely to be found "at the farm gate". Field trial data generally represent unwashed, whole commodities rather than the washed, edible portion of a commodity represented by monitoring data such as that generated by the Pesticide Data Program (PDP) which is used for dietary risk assessment.

5) As stated in your rule, "Without a tolerance or exemption, pesticide residues in or on food is considered unsafe, 21 U.S.C. 346a(a)(1), and such food, which is then rendered "adulterated" under FFDCA section 402(a), 21 U.S.C. 342(a), may not be distributed in interstate commerce, 21 U.S.C. 331(a)." Assuming that no residues exist in or on food, does it need a tolerance or exemption to enter interstate commerce?

a. In sum, while sugar beets may be treated with chlorpyrifos, none of the products (crystallized sugar, dried pulp, molasses) sold into commerce have residues, so may they be distributed via interstate commerce?

b. Is EPA aware of any other commodities that also fall in this distinct category?

Agency Response: The FFDCA prohibits the introduction of adulterated food into interstate commerce. Adulterated food includes any food that contains pesticide residues not covered by a tolerance. If there are no pesticide residues, then the food would not be adulterated. The Agency's available data indicate that sugar beets treated with chlorpyrifos will have pesticide residues "at the farm gate" and thus need a tolerance.

6) In the event sugar beets continue to be considered by EPA as "food-uses," uncertainty still rests in that classification.

a. Has EPA considered that sugar beets are unique in that they are not consumable as "foods" in raw form, and zero commerce takes place between harvest and processing? This is unique from other "food uses" subject to the final rule.

b. Objectively, should an input that is never intended to be consumed or enter commerce really be classified as a food?

Agency Response: Use on sugar beets is considered a food use because products derived from it are considered human food and animal feed; therefore, tolerances are required. For more information, please see above response to question #2.

Current Crop:

7) While our products do not contain residues, given that EPA has historically assigned tolerances we have an interest to ensure any forthcoming guidance with EPA and FDA provides clear understanding of what may or may not be considered adulterated. EPA's rule states that "any residues of these pesticides

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in or on such food shall not render the food adulterated so long as it is shown to the satisfaction of the Food and Drug Administration that:

1. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA, and

2. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance that was in effect at the time of the application. Evidence to show that food was lawfully treated may include records that verify the dates when the pesticide was applied to such food."

a. For example, sugar beets grown in 2021 and that are set to be processed from this growing season, and from past growing season, will have been treated lawfully with chlorpyrifos will be processed well into 2022. Assuming there is no allowable future use of chlorpyrifos, will FDA provide guidance that these products do not need to be segregated while awaiting processing? Given the millions of tons of sugarbeets affected, segregation would be virtually impossible. Will EPA and FDA work to clarify this language to ensure it provides certainty for both food and feed uses and so that sugarbeet products have the presumption of satisfying the requirements of FDA outline above? For example, could EPA and FDA provide guidance that such foods may be processed in the ordinary course by producers and/or third-party processors and any resulting food or feed products shall likewise not be considered adulterated? Could EPA and FDA provide blanket guidance that commodities harvested under a lawful manner under FIFRA be processed and not be considered adulterated without the need for new record keeping requirements?

Agency Response: It is the timing of application that determines whether food treated with chlorpyrifos is adulterated. Until the date the tolerances expire, chlorpyrifos may be used on food commodities in accordance with label directions and the existing tolerances. Residues of chlorpyrifos in or on the food after the tolerances expire would not render the food adulterated as long as those conditions are met. After the tolerances are revoked, application of chlorpyrifos will render any food so treated adulterated and unable to be distributed in interstate commerce. Food in the channels of trade that was treated prior to the expiration of the tolerances would be governed by section 408(l)(5) of the FFDCA, which describes conditions that must be met in order for such food to be distributed. EPA has been working closely with FDA on a guidance for treated commodities in the channels of trade.

b. How is EPA coordinating with your sister agencies at the Association of American of Pesticide Control Officials to ensure that enforcement will be consistent with federal intent and will not create new record keeping requirements?

Agency Response: EPA met with representatives from AAPCO on Wednesday, August 18, 2021, the day of pre-publication of the final tolerance rule, to discuss the rule and answer questions. EPA representatives also presented at the SFIREG Joint Meeting of the Environmental Quality Issues (EQI) and Pesticide Operations and Management (POM) Committees on Monday, September 20, 2021, to discuss the final tolerance rule and answer questions.

Existing Stocks:

8) After the tolerance revocation takes effect in 6 months, would EPA consider continued use of chlorpyrifos via an "Order Governing Existing Stocks to be used in conjunction with the tolerance revocation?"— either for sugar beets until the aforementioned arguments are resolved or for growers more broadly?

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Agency Response: Existing stocks is a term under FIFRA generally used in connection with the pesticide products that have been released for shipment as of the date a product registration is cancelled. EPA has not cancelled any chlorpyrifos products as a result of the final tolerance rule; therefore, there are no existing stocks at this time.

The tolerance rule issued on August 30, 2021, does not prohibit sale and distribution of registered pesticide products. However, once the tolerances expire and are revoked in six months, sale and distribution of chlorpyrifos products labeled for use on food crops would be considered misbranded; therefore, it would be a violation of FIFRA to sell and distribute those products. Once the tolerances are revoked, there is no provision for continued use of product.

EPA intends to cancel registered food uses of chlorpyrifos associated with the revoked tolerances under FIFRA, as appropriate. That cancellation action would only address the registered food uses of chlorpyrifos; it would not impact nonfood uses of chlorpyrifos, including public health uses for mosquito control and USDA quarantine use for fire ant control. EPA will continue to evaluate the non-agricultural, non-food uses as part of the ongoing registration review for chlorpyrifos. Following the cancellation of food uses, there may be some products that have label instructions for both food and non-food uses. Those labels would need to be amended to remove any food-uses that were cancelled.

Additionally, a registrant, including those of chlorpyrifos, can cancel the registration of a pesticide product or use at any time by voluntarily submitting a request to the Agency.

Drinking Water Analysis:

9) EPA's assessment discusses impacts on drinking water for determining risk (i.e., drinking water exceeds 4 ppb (DWLOC) which is the exposure level determined safe for children)

— a. EPA does not explain how you reached that 4 ppb as a safe standard. Could you elaborate on how you reached that number?

Agency Response: Please see Section 7.0 Aggregate Exposure/Risk Characterization of the 2020 Human Health Risk Assessment, which starts on page 44, which covers the specifics of deriving the drinking water level of comparison (DWLOCs) (calculations are in the footnotes of the tables). The 2020 Human Health Risk Assessment can be found at the following link:[HYPERLINK "https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944"].

— b. This document cites "Chlorpyrifos Refined Drinking Water Assessment for Registration Review" (Ref 28) to justify revocation of tolerance as it demonstrates the DWLOC exceeds 4 ppb. In this document EPA states:

— i. The EPA acknowledges in the body of Ref 28 that the models used overestimate water contamination (e.g., assume highest label rates and lowest application intervals) and further explain the actual exposure is more sporadic as well as spatially and temporally variable.

— ii. Although the document concludes chlorpyrifos concentrations "could be greater than 100 ppb (100 ug/L)" those assumptions are "based off of peak values from models derived from the highest label rate crops (tart cherries)." Looking at the model averages for more representative crops (bulb onions) the concentration drops to 0.8 ppb (0.8 ug/L) far below the DWLOC.

— iii. The document (Ref 28) shows extensive data collected measuring actual presence of chlorpyrifos in surface water. The highest number collected was 2.1 ppb (half of the DWLOC), but most were under 0.3 ppb. These numbers dropped significantly following filtration (standard practice in water treatment) since chlorpyrifos can adsorb to particulate.

— iv. The document (Ref 28) also states "…there were no detections of chlorpyrifos- oxon in paired finished water samples from the PDP monitoring program. Tierney et al., 200394 also did not detect chlorpyrifos in finished water at community water systems."

c. If EPA uses PDP monitoring to justify the lack of threat from food residue, why does it ignore the PDP data to justify a lack of risk from drinking water?

Agency Response: EPA has considered available PDP monitoring data for chlorpyrifos in drinking water. Evaluation of PDP data is described in the [HYPERLINK "https://www.regulations.gov/document/EPA-HQ-OPP-2015-0653-0437"], *which can be found at the following link:* [HYPERLINK "https://www.regulations.gov/document/EPA-HQ-OPP-2015-0653-0437"]. *In summary, samples from raw intake water (source water) as well as finished drinking water are analyzed as part of the PDP, typically on a bimonthly basis. Samples have been collected from 82 locations in 28 states and the District of Columbia; however, only a subset of these sampling locations are sampled each year. Furthermore, although sampling sites fall within pesticide use areas, sample collection was not designed to specifically coincide with pesticide applications.*

EPA acknowledges that the highly censored nature, i.e., many non-detects, of the monitoring data available for chlorpyrifos and chlorpyrifos-oxon make it difficult to interpret the data. Non-detects could be the result of an inadequate sampling frequency, lack of use in the watershed, local meteorological conditions not conducive to runoff prior to sample collection, or sampling did not coincide with the chlorpyrifos application window. The limited number of site-years and limited sample frequency limits the utility of the PDP data for estimating concentrations of chlorpyrifos and chlorpyrifos-oxon in drinking water. Consistent with the 2019 FIFRA SAP on the Approaches for Quantitative Use of Surface Water Monitoring Data in Pesticide Drinking Water Assessments, EPA addressed sampling frequency with sampling bias factors and SEAWAVE-QEX in the [HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0850-0941" \h], *which can be found at the following link:* [HYPERLINK "https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0941" \h].

d. Is EPA aware biological monitoring reported in the peer-reviewed literature shows infants and small children only routinely being exposed to 0.5 ppb chlorpyrifos through nonoccupational exposure and concluded "exposure has been overstated by more than 1000-fold"?

Agency Response: The Agency completed an extensive review of the literature for chlorpyrifos. All pertinent data that would affect our risk assessment were incorporated into our assessment. Without knowing what specific data is being referred to here, the Agency cannot comment further.

Future Uses:

10) Does EPA plan to start a new registration process that may provide new restrictions on chlorpyrifos use?

a. Will this use the current decision documents including the 2020 PID, or will EPA be altering course in light of the 9th Circuit's decision?

Agency Response: EPA does not initiate registration actions in general and does not plan to start a new registration process for the food uses of chlorpyrifos.

b. Will EPA be reproposing for comment the Chlorpyrifos Proposed Interim Registration Review Decision from December 2020, especially in light of all the changes in the August 18, 2021, pre-published final rule on Chlorpyrifos; Tolerance Revocations?

Agency Response: EPA will continue to evaluate the non-agricultural, non-food uses as part of the ongoing registration review for chlorpyrifos, with the Interim Decision expected to be completed by October 2022. EPA does not intend to release a revised PID for comment.

11) Further, is EPA considering registering the pesticide as Restricted Use Products with increased restrictions?

Agency Response: EPA will continue to evaluate the non-agricultural, non-food uses as part of the ongoing registration review for chlorpyrifos, which is expected to be completed by October 2022. If the Agency determines that the pesticide, when applied in accordance with the label's directions for use, warning and cautions, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects, the Agency will classify the pesticide as an RUP. FIFRA 3(D)(1)(c). The Agency did not make that determination at the time of the PID, but if comments are received relevant to consideration of changes to the proposed mitigation, they will be addressed in the interim decision.

12) If chlorpyrifos is no longer an option for insect control, we are limited to just two labeled post-emergence liquid insecticide options that are both pyrethroids for sugarbeet root maggot control. These pyrethroids are not as effective and do not perform well in warmer temperatures above 80 degrees F. Only using and having available the one mode of action can lead to insect resistance to the pyrethroid chemistry as well.

Has EPA considered whether there are viable alternatives for chlorpyrifos in different crops and, if so, does the agency plan to provide the public with that analysis?

a. Has EPA considered that losing more and more pesticides with different mode of actions will complicate Integrated Pest Management, complicate proper rotation of different modes of action, and with that increase the likeliness of insecticide resistance?

b. Has EPA considered the effects on sustainability, carbon footprint and farm economics? Soft chemistries (pyrethroids) would require more frequent applications, with that an increase in fuel consumption, soil compaction, and a potential decline of beneficial insects (based on more frequent applications)?

Agency Response: Under the revisions mandated by the FQPA, EPA cannot consider benefits in FFDCA decisions. However, as part of the registration review process under FIFRA, the Agency did evaluate the benefits of chlorpyrifos to growers by crop. The economic benefits to growers are equivalent to the losses they face without chlorpyrifos. This analysis is available in a supporting memorandum in the chlorpyrifos regulatory docket, which is available at the following link: [HYPERLINK "https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0969" \h]. *Sugarbeets was one of several crops discussed in some detail in this document, and EPA acknowledges that it concluded that until suitable alternatives can be adapted to replace chlorpyrifos, sugarbeet yields in production areas of the upper Midwest Red River Valley region could be reduced due to increased problems with the sugarbeet root maggot. EPA is aware that IPM and resistance management are critical pest management benefits of many pesticides, and where benefits considerations are permitted by law, the Agency takes these aspects into serious consideration.*

13) Would EPA consider honoring future Section 18 Emergency Exemption Requests for chlorpyrifos—either for sugar beets or for growers more broadly?

Agency Response: Section 18 of FIFRA allows EPA, when emergency conditions exist, to exempt states and federal agencies from the provisions of FIFRA, including the requirement that pesticides must be registered to be sold or distributed. Since at this time, registrations of chlorpyrifos have not been cancelled, no section 18 exemption would be necessary to allow sale and distribution. An emergency exemption cannot reinstate the tolerances under the FFDCA; emergency exemptions only address the sale, distribution, and use of a pesticide under FIFRA. Should EPA receive a request for a section 18 emergency exemption after the food uses for chlorpyrifos are cancelled under FIFRA, EPA would need to establish a time-limited tolerance under FFDCA 408(l)(6). EPA can only establish such a tolerance to cover residues of the pesticide applied under a section 18 emergency exemption if it can determine that the tolerance is safe, as defined by the FFDCA. If EPA cannot determine the tolerances would be safe, EPA cannot establish the tolerances and thus, EPA would not be able to grant a section 18 emergency exemption request.

OMB Process Issues:

14) The final rule states, "The Office of Management and Budget (OMB) has exempted tolerance regulations from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866 (EO 12866), this final rule is not subject to Executive Order 13563 (76 FR 3821, January 21, 2011). B. Paperwork Reduction Act (PRA)."

EPA's posted final rule renders food tolerances more stringent than the status quo and according to previous USDA estimates, and EPA's December 2020 PID, chlorpyrifos has an economic impact over $100 million. Revoking chlorpyrifos tolerances seems to fit the requirements of EO 12866.

a. Why wasn't this rule considered a "significant regulatory action," that should have been subject to interagency review?
b. When will EPA put this rule back out for public comment to comply with the EO?
c. When will EPA be sending the final rule back to OMB for interagency review?

Agency Response: The Agency published a benefits memo from late 2020 that estimated the benefits of chlorpyrifos in agriculture, which is how the Agency would estimate the cost of revoking the tolerances. These estimates reflect significant uncertainty. The court-ordered deadline that the Agency was subject to comply with for this action resulted in the rapid timeline for this final rule. At this time, the Agency intends to proceed in accordance with the process laid out in FFDCA section 408(g).

Follow up questions:

1. Where should we send information on our non-residue data to EPA?

Agency Response: The non-residue data to support reconsideration of status would be subject to review under PRIA. Please find more information on how to submit as a PRIA action at the following link: [HYPERLINK "https://www.epa.gov/pria-fees/fy-2020-2021-fee-schedule-registration-applications"] *and/or please contact the Registration Division.*

2. We are also reaching out to USDA for their data too. Please confirm that the below is the appropriate contact at USDA.

a. **Julie A. Chao, M.A., MSPH**
Regulatory Risk Assessor
[HYPERLINK "https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.usda.gov%2Foce%2Fpest%2Fjulie.chao%40usda.gov&data=04%7C01%7CGrable.Melissa%40epa.gov%7C98ecdcdd7b584d17f07e08d97406e2e4%7C88b378b367484867acf976aacbeca6a7%7C0%7C0%7C637668395204348625%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=ztEIg8j6rpHojY%2F8mK8FumRsyfmpTFNeNsR1CY33Pjw%3D&reserved=0"]

Agency Response: Julie Chao is the correct contact at USDA.

3. Can you provide a timeline for responding to the questions addressed in the letter sent on Tuesday evening (attached again for convenience)?

   Agency Response: This document provides the responses to the questions in the letter.

4. Can you provide us with the list of contacts you are in discussions with at FDA so we can also engage with them?

   Agency Response:
   Center for Food Safety and Applied Nutrition at the US FDA ([HYPERLINK "mailto:CFSANTradepress@fda.hhs.gov" \h]*)*
   Alice Chen ([HYPERLINK "mailto:alice.chen@fda.hhs.gov"]*)*
   Charlotte Liang ([HYPERLINK "mailto:Charlotte.Liang@fda.hhs.gov"]*)*
   Lauren Robin ([HYPERLINK "mailto:Lauren.Robin@fda.hhs.gov"]*)*
   Carie Jasperse ([HYPERLINK "file:///\\\\W1818TDCEC025.aa.ad.epa.gov\\OPP-AD-USER$\\mgrable\\MMG\\PRD\\Chlorpyrifos\\carie.jasperse@fda.hhs.gov"]*) (Counsel)*

5. Can you point us to where the 4ppb tolerance in the water model came from? As mentioned on the call yesterday, a couple of our scientists wanted to understand that issue better and couldn't find it in the document referenced on the call.

   Agency Response: Please see Section 7.0 Aggregate Exposure/Risk Characterization of the 2020 Human Health Risk Assessment, which starts on page 44, which covers the specifics of deriving the drinking water level of comparison (DWLOCs) (calculations are in the footnotes of the tables). The 2020 Human Health Risk Assessment can be found at the following link:[HYPERLINK "https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944"]. *Please refer to table 7.2.2 in revised* [HYPERLINK "https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944"]. *In the footnote, the formula provided for the calculation is:*
   DWLOC: DWLOC ppb= PoDwater (ppb; from Table 4.2.2.1.2) /MOEwater

If you have further questions regarding this matter, please contact Alexandra (Alex) Feitel at [HYPERLINK "mailto:feitel.alexandra@epa.gov"] or 703-347-8631, or Melissa Grable at [HYPERLINK "mailto:grable.melissa@epa.gov"] or 703-308-3953.

Sincerely,

Edward Messina, Esq.
Director

Cc: Loni Cortez Russell, Office of Public Engagement and Environmental Education

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