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Dr. Michal Ilana Freedhoff
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20004

Re: EPA Final Rule Revoking All Chlorpyrifos Tolerances

Dear Assistant Administrator Freedhoff:

As you know, the Environmental Protection Network (EPN) is an organization of over 550 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of EPA, public health, and the environment. EPN appreciates and applauds the hard work of EPA that culminated in the Final Rule (published in the Federal Register on August 30, 2021) revoking all food tolerances for the pesticide chlorpyrifos effective February 28, 2022. Implementation of this Rule will not be simple, and EPN submits the following recommendations in the hope that we may assist the agency in diminishing the likelihood that chlorpyrifos residues will continue to enter the food supply after the tolerance revocations become effective on February 28, 2022.

Actions EPN Recommends EPA Take to Alert Users to the Consequences of the Tolerance Revocations

As you know, EPA regulates pesticides in the United States under two different statutes: the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Under the FFDCA, EPA establishes allowable levels for pesticide residues in food through the issuance of tolerances. Tolerances are regulations that establish maximum limits for allowable pesticide residues in food and feed commodities. A commodity containing a pesticide residue not covered by a tolerance or that exceeds the tolerance level established for the commodity is generally considered adulterated and unsafe under the FFDCA and may not be sold in commerce. Under FIFRA, EPA regulates the sale and use of pesticide products in the United States. This regulation primarily occurs through the pesticide registration process; as a general matter, unregistered pesticides may not be sold or distributed in the United States, and registered pesticides must be used according to the terms and conditions of their EPA-approved labeling.

Under the FFDCA, EPA may only establish or leave a tolerance in effect if the agency determines "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical, including all anticipated dietary exposures and all other exposures for which there is reliable information." §408(b)(2)(A); 21 U.S.C. §346a(b)(2)(A). Under FIFRA, EPA's primary focus on whether to allow a pesticide applicant or registrant to obtain or keep a registration depends on whether the use of the pesticide will generally cause "unreasonable adverse effects on the environment," although FIFRA also requires EPA to

determine, among other things, that the pesticide's "labeling ... compl[ies] with the requirements of [FIFRA]." (§3(c)(5); 7 U.S.C. §136a(c)(5).

There are important linkages between the FFDCA and FIFRA to assure that pesticide regulation operates effectively and efficiently across the two statutes. The FFDCA directs EPA to coordinate activities across the two statutes when EPA revokes pesticide tolerances (under the FFDCA) or cancels registrations, in whole or in part, due to human dietary risks (under FIFRA). §408(l)(1) and (2); 21 U.S.C. §346a(l)(1) and (2). Under FIFRA, the definition of "unreasonable adverse effects on the environment" includes "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with [the FFDCA's reasonable certainty of no harm standard]." §2(bb)(2); 7 U.S.C. §136(bb)(2). And EPA's implementing regulations for pesticide registration provide that EPA shall not register a pesticide product unless "all necessary tolerances" are in place. *See*, e.g., 40 CFR §152.112(g).

One of the purposes of the linkage between the two statutes is to prevent the type of situation that will be presented by chlorpyrifos use on food after tolerances are revoked in 2022. Under the FFDCA, any food treated with chlorpyrifos after tolerances are revoked and containing detectable residues of the pesticide is considered "unsafe" and therefore "adulterated"; adulterated food may not be introduced into the food supply and is subject to seizure by the Food and Drug Administration (FDA). *See* §§408(a)(1), 402(a), 304, 301(a); 21 U.S.C. §§ 346a(a)(1), 342(a), 334, 331(a). While these FFDCA provisions mean that chlorpyrifos use after tolerance revocation would render treated food with detectable residues unlawful for sale, the FFDCA only governs the treated food. Use and sale of the pesticide can only be addressed under FIFRA through the provisions of section 6 (7 U.S.C. § 136d). EPN appreciates that cancellation of affected uses (unless registrants submit voluntary cancellation requests) is unlikely to become final until well after the use of chlorpyrifos begins next year. Thus there is a very real possibility that chlorpyrifos products will be available for sale and use will be lawful during the 2022 growing season, even if any food treated with chlorpyrifos after revocation would be "unsafe" and "adulterated" under the FFDCA and subject to various actions by FDA.

While EPN does not believe EPA has sufficient time to complete the FIFRA process to outlaw the use of chlorpyrifos in 2022 on crops for which tolerances will have been revoked, EPN does recommend that EPA take practical steps that could make it much less likely that unlawful residues of chlorpyrifos will find their way into the nation's food supply. Specifically, EPA should consider promptly undertaking a general communication strategy directed at informing users about the need to cease chlorpyrifos use as soon as possible, but no later than February 28, 2022, and the agency could inform registrants of chlorpyrifos products that they must quickly begin to alert users, through amended labeling or other comprehensive actions, to the consequences of applying chlorpyrifos to crops after the effective date of the revocations.

EPN agrees with EPA that chlorpyrifos products labeled for food or feed use, but without an appropriate warning of the consequences of using the product after February 28, 2022, are misbranded. EPN further believes that those products are misbranded today, given the likelihood that much of the chlorpyrifos sold after today will not be used entirely before March 1, 2022.

As you know, a pesticide is misbranded if, among other things, "its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular." FIFRA §2(q)(1)(A); 7 U.S.C. §136(q)(1)(A). It is unlawful for any person under FIFRA to sell or distribute a pesticide that is "misbranded." §12(a)(1)(E); 7 U.S.C. § 136j(a)(1)(E). EPA is authorized to issue a stop sale, use, or removal order (SSURO) to prevent unlawful sale or distribution of a pesticide. §13(a); 7 U.S.C. §136k(a).

EPN recommends that the agency act promptly to ensure that anyone holding a chlorpyrifos product fully understands that use of the product after February 28, 2022, on a crop for which the tolerance has been revoked will render the treated food adulterated. Therefore, EPN recommends that EPA immediately communicate to potential users that treating crops with chlorpyrifos after February 28, 2022, could result in the harvested commodities being deemed adulterated and subject to seizure by FDA.

Because general communications directed at potential users may not reach everyone who purchases a chlorpyrifos product, EPN also recommends that EPA now take steps to inform registrants and distributors of chlorpyrifos that EPA considers any chlorpyrifos product containing directions for use on food to be misbranded unless the label also contains a very clear and accurate warning of the legal status of any food treated after February 28, 2022. EPN further recommends that EPA issue appropriate SSUROs if registrants or distributors decline to take appropriate steps within a suitably brief period of time to prevent the sale and distribution of misbranded chlorpyrifos products.

The case for misbranding here is clear. As noted, EPA's regulations require (and have so required for many years) that pesticide registrations may not be issued unless necessary tolerances are in place. In the agency's reviews of applications for pesticide registration, EPA carefully determines that use of a pesticide according to label directions will not result in residues in food nor on any crop that exceed tolerance levels. As a result, agricultural producers have long been able to confidently rely on pesticide labels when producing food; if any pesticide is applied according to labeling directions, treated food will be within tolerance levels and can lawfully be introduced into commerce.

This paradigm will uniquely no longer apply to chlorpyrifos products after February 28, 2022; growers could follow label directions impeccably and be left with crops that they cannot lawfully sell. Under these circumstances, EPN believes that existing chlorpyrifos labels are misleading in a very important particular: many growers are very likely used to relying on pesticide labels to assure FFDCA compliance, but that reliance will no longer be appropriate if a grower follows the chlorpyrifos directions for use after February of 2022. In short, the existing language on chlorpyrifos labels has a high potential of misleading growers into believing that compliance with the existing label would result in tolerance-compliant crops, when in fact label compliance could lead to crops containing residues which would not be in compliance with the FFDCA.

EPA encountered this situation once before. In May of 2009, EPA issued a final rule revoking all food tolerances for the pesticide carbofuran. *See* 74 Fed.Reg. 23045 (May 15, 2009). That revocation rule had an effective date of August 13, 2009, with the actual revocation of tolerances delayed until December 31, 2009.

EPA did not expect carbofuran registration cancellations to occur in 2009, and was concerned about the potential for carbofuran to be applied to crops in 2010 and result in adulterated food. Decision-makers at EPA considered a number of options, and eventually elected to take the policy position that carbofuran products would be deemed misbranded if labels did not contain a strong warning that use of carbofuran in 2010 (and beyond) would likely result in crops containing residues that would render the crops adulterated and unlawful for sale. This policy position was discussed orally with the main carbofuran registrant, but in the end, the registrant agreed to remove carbofuran products expeditiously from the channels of trade unless and until appropriate tolerances were in place. In view of the registrant's voluntary action, the EPA never felt the need to memorialize its policy position in writing or make a final determination on whether to issue SSUROs to prevent the sale of misbranded carbofuran products.

A judicial decision limiting EPA's misbranding authority was issued in 2011, and EPN expects that chlorpyrifos registrants might argue that the decision in *Reckitt Benckiser v. Jackson* (D.D.C. January 28, 2011) (762 F.Supp.2d 34) prevents EPA from treating chlorpyrifos registrations as misbranded. EPN submits that such an argument goes far beyond the decision in *Reckitt*, and that EPA could and should reject the argument if it is made.

The *Reckitt* case arose out of the reregistration decision for certain rodenticide products. While the reregistration decision for rodenticides involved additional litigation and took a number of twists and turns, the Final Risk Mitigation Decision (RMD) (in essence, the final reregistration determination) for rodenticides concluded that affected rodenticide products could only meet the FIFRA standard for registration if, *inter alia*, residential rodenticides were only used in child-proof bait stations (and physically formulated to remain in bait stations if the stations were physically jostled or shaken) and certain active ingredients were replaced by other rodenticide ingredients. Affected registrants were directed to submit applications for amended registration to conform to the terms of the RMD or to submit voluntary cancellation requests; registrants that chose to do neither were informed that, after a certain date, EPA would feel free to initiate cancellation action under FIFRA section 6 or to commence appropriate enforcement action because EPA would consider the products to be misbranded. The registrants requested that EPA initiate a cancellation proceeding, and when no proceeding was started, filed suit challenging EPA's determination that it could essentially implement the RMD through misbranding enforcement action instead.

The misbranding provisions at issue in the *Reckitt* case were those set forth in FIFRA section 2(q)(1)(F) and (G) (7 U.S.C. §136(q)(1)(F) and (G)).[1] Both of those provisions center on whether label language is adequate to protect human health and the environment. The plaintiffs in *Reckitt* argued that the cancellation provisions of FIFRA provide the sole remedy when EPA determines that the conditions of registration of a

[1] Section 2(q)(1)(F) provides that a pesticide is misbranded if "the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and, if complied with, together with any requirements imposed under Section 3(d) of [FIFRA], are adequate to protect health and the environment." Section 2(q)(1)(G) provides that a pesticide is misbranded if "the label does not contain a warning or caution statement which may be necessary and, if complied with, together with any requirements imposed under Section 3(d) of [FIFRA], is adequate to protect health and the environment."

registered product are no longer sufficient to protect human health and the environment; EPA argued that Congress, through FIFRA, provided two similar provisions (misbranding and cancellation) to address unsafe pesticide products and that the agency retained the discretion to pursue either provision. The court ruled in favor of the registrants, essentially finding that a ruling in favor of EPA would allow the agency to "bypass" the cancellation provisions and effectively "cancel" products without providing registrants with the hearing protections laid out in section 6 of FIFRA.

While EPN does not necessarily agree with the District Court's reasoning in *Reckitt*, there are significant differences between the chlorpyrifos situation and that of the rodenticides. In the case of the rodenticides, EPA had concluded, after a long reregistration process, that the FIFRA registrations did not meet the standards for registration and that important changes needed to be made to the registrations. These changes could not be accomplished through changes to label language; EPA had directed registrants to change the physical form and packaging of the products and, in some cases, to change active ingredients as well. EPA had traditionally always pursued the cancellation process set forth in FIFRA to implement its decisions after reviewing whether pesticides continued to meet the standards for registration. And the particular misbranding provisions at issue in the *Reckitt* case were conceded by EPA to be very similar to the standard for commencing a cancellation action.

In the case of chlorpyrifos, EPA would not be seeking to accomplish cancellation by another route. Nor would EPA be seeking through the misbranding process any changes to the underlying registrations. The misbranding provision EPN recommends EPA use here, the "false or misleading in any particular" provision embodied in section 2(q)(1)(A), is very different than the provisions at issue in the *Reckitt* case (2(q)(1)(F) and (G)). In particular, registrants can avoid misbranding issues for chlorpyrifos labels by adding appropriate language on the label to make sure that a grower understands usage on food crops in accordance with the labeling would likely result in adulterated food. EPN recommends that EPA cannot, and should not try to, prohibit chlorpyrifos use through application of the misbranding provision. Consistent with the statutory policies linking FFDCA and FIFRA, EPN recommends that EPA assure that growers are not misled into thinking that proper label use will result in FFDCA-compliant food, and that the *Reckitt* decision should not be read as preventing EPA from assuring that chlorpyrifos labels do not mislead growers.

In sum, EPN recommends that EPA quickly start the process of communicating to registrants and distributors of chlorpyrifos that the agency believes the chlorpyrifos labels are misleading (and therefore could be considered misbranded), and invite any person who wishes to continue selling or distributing chlorpyrifos that could be used after February 28, 2022, to make suggestions on how to revise the labels (or take other appropriate steps) so that all growers are aware of the true FFDCA-related status of crops treated in 2022 and beyond.

EPA Assistance to FDA in Enforcement of the Tolerance Revocations

Beyond EPN's recommendations on the actions the agency could take directly affecting the sale and distribution of pesticide products containing chlorpyrifos, EPN also recommends that EPA collaborate with the FDA on its efforts to enforce the prohibition against sale and distribution of food and feed products containing illegal residues of chlorpyrifos. As detailed below, EPN thinks that EPA should provide FDA with policy suggestions on how to distinguish between legal and illegal residues in commodities with detectable levels of chlorpyrifos. In addition, EPN recommends that EPA give FDA information that would assist in targeting its chlorpyrifos enforcement efforts efficiently.

As mentioned earlier and by way of background, the FFDCA "pass through" provision in sec. 408(l)(5) (21 U.S.C. §436a(l)(5)) provides that a food or feed commodity containing a residue of a pesticide chemical for which the tolerance has been revoked shall not be deemed adulterated if "it is shown to the satisfaction of the Secretary" [of Health and Human Services] to meet two criteria. Specifically, a commodity would not be deemed to be adulterated if: (1) the residue does not exceed the tolerance applicable at the time the pesticide was used and (2) the residue is the result of use of the pesticide at a time when such use was legal under FIFRA.[2] Assuming EPA does not act to cancel the registration of chlorpyrifos products,[3] this means, as a practical matter, that the residues in a treated commodity are legal only if the use of the pesticide occurred prior to the revocation of the tolerances and the residues are consistent with the levels established in those tolerances. (Absent EPA action, use after the revocations take effect would still be legal, but the applicable tolerance for the time of application would be zero.) Therefore, to implement the "pass through" provision, EPN recommends that FDA provide guidance to entities who may be distributing food and feed items that, after the effective date of the tolerance revocations, may contain detectable residues of chlorpyrifos. FDA's traditional analysis of commodity samples will address one part of the criteria — whether the residue level does not exceed the previously established tolerance level for chlorpyrifos. But there is a need for FDA guidance to clearly explain what documentation would demonstrate, to FDA's satisfaction, whether the commodity was legally treated prior to the revocation of chlorpyrifos tolerances.

As the agency did in the case of methyl parathion, EPN recommends that EPA consult with FDA regarding the guidance on how to satisfy FDA that crops were treated while the tolerances were still in effect. EPN

[2] The EPA Administrator has discretion to determine that the "consumption of legally treated food . . . will pose an unreasonable dietary risk" and thereby to disallow the application of the "pass through" provision. EPN thinks that the administrative record described in EPA's Final Rule revoking tolerances for chlorpyrifos would not support such an EPA finding. The agency's Final Rule states that the risks attributed only to chlorpyrifos residues in food are limited and indicate that, by themselves, those risks would be acceptable. According to EPA's risk assessment, exposure from residues in food would contribute less than 5% of the Population Adjusted Dose, the level that EPA's Final Rule used to assess safety.

[3] Although EPA has not yet acted to cancel the registration of food uses of chlorpyrifos, several states have acted to restrict use within their states. The Hawai'i legislature banned use of chlorpyrifos, effective in 2019, and New York and California initiated administrative rulemakings to phase out sales and most of its uses. In addition, Maryland has enacted a limited prohibition on the use of chlorpyrifos. Since FIFRA sec. 24 authorizes states to prohibit use of a pesticide that is allowed by EPA, use in violation of these state actions may not be "legal under FIFRA," and arguably would make the "pass through" provision inapplicable to food or feed commodities containing chlorpyrifos residues as a result of such use.

expects FDA's guidance would instruct entities selling or distributing food and feed commodities potentially bearing chlorpyrifos residues after the effective date of the revocation on what records they should obtain and keep. EPN also recommends that EPA explain how existing record-keeping requirements for restricted-use pesticides, like chlorpyrifos, could be used to help demonstrate that the pesticide application occurred while the tolerances were still effective. Because chlorpyrifos products are classified for restricted use, chlorpyrifos use is limited only to individuals who are certified applicators or individuals working under the direct supervision of a certified applicator. Certified commercial applicators are required to keep records of the amounts, uses, dates, and places of each application of a restricted-use pesticide that they and the individuals they supervise make. Thus, since many chlorpyrifos users already keep detailed records of the use of chlorpyrifos on food and feed crops, FDA could reasonably require entities distributing chlorpyrifos-treated commodities to obtain such records from the applicators and, following FDA's guidance on procedures for traceability, to associate those records with specific, traceable quantities of treated commodities. The FDA guidance may also include a requirement that there be documentation showing if quantities of a commodity legally treated with chlorpyrifos were segregated from other quantities of the commodity so that the "pass through" protection is not mistakenly given to a commodity treated after the revocation took effect.

EPA also can and EPN recommends should provide FDA with information that will help it better target its enforcement efforts. Once the revocation of chlorpyrifos tolerances takes effect, EPN expects FDA will expand its monitoring of food and feed commodities, as well as its review of the documentation specified in its guidance, as needed, to demonstrate that lawful treatment pre-dated the revocations, to detect the presence of illegal chlorpyrifos residues. At least in the short run, however, FDA will need to be able to anticipate whether the "pass through" provision applies to a commodity with detectable residues of chlorpyrifos. Using information on which commodities are likely to have been treated pre-revocation and yet to have residues at detectable levels post-revocation, EPA can recommend to FDA on which commodities and when FDA should focus its enforcement efforts.

EPA has several different types of data that could inform whether a particular commodity is likely to have residues covered by the "pass through" provision. Specifically, EPA could use label directions on the allowed timing of chlorpyrifos applications, together with data from residue field trials and residue dissipation studies, to predict how long after treatment a chlorpyrifos residue would be detectable in different treated commodities. The agency could also refine such estimates with information on typical agricultural practices, for example, the extent to which legal use of chlorpyrifos would likely take place during the months between September 2021 and the effective date of the revocation, currently February 28, 2022.[4] In addition, EPA has test results on the effects of processing on chlorpyrifos residues. Using those studies, the agency could

[4] Under EPA's Final Rule, the revocation of chlorpyrifos tolerances would become effective early in 2022, before most growers would start using chlorpyrifos in 2022. Because most use of chlorpyrifos begins in the spring and lasts through the summer, any stay of that effective date for the revocations would likely result in a significant increase in the amount of food treated with chlorpyrifos that would be protected by the "pass through" provision. For that reason, among others, EPN would oppose all requests for a stay of the effective date of the revocation.

predict whether commodities that have been processed are likely to contain higher or lower concentrations of chlorpyrifos than the raw forms of the commodities. The agency could also use data on the percent of crop treated, together with data from the U.S. Department of Agriculture's (USDA's) Pesticide Data Program, to predict the commodities that will more frequently have detectable residues. Finally, EPA and FDA could work together to obtain information from processors about how quickly different forms of raw and processed commodities move through the supply chain.

With such information from EPA, FDA could reasonably predict which commodities and which forms of a commodity are likely to have been lawfully treated with chlorpyrifos prior to the revocation and, after the revocation of tolerances takes effect, for how long they could be expected to retain a detectable level of residue. Such commodities presumptively would qualify under the "pass through" provision. Other commodities, presumptively, would not. FDA could then target its monitoring programs at the commodities where potential violations were a greater concern.

Request for Meeting with EPA

EPN appreciates and supports the Final Rule that EPA issued revoking all tolerances for chlorpyrifos, and looks forward to the agency taking quick and aggressive actions to implement the goal of the final rule—the protection of the public from unsafe chlorpyrifos residues in food and drinking water. We would be happy to meet with EPA to answer any questions the agency may have about the recommendations in this letter.

Also, we would like to meet with you to discuss how the agency's rationale for the Final Rule relates to additional regulatory actions that EPA needs to consider. The Final Rule contains an explanation that, in the eyes of some stakeholders, indicates the possibility that the agency could establish tolerances for a limited subset of chlorpyrifos uses. While that may not be what EPA intended to communicate, we would like to explain why we question whether the current scientific database could support a finding that any chlorpyrifos tolerance is safe. In addition, although EPN was not among the organizations that sponsored the original petition seeking the revocation of chlorpyrifos tolerances, EPN thinks that EPA still needs to address the additional actions sought by the petitioners—the cancellation of all remaining non-food use registrations of chlorpyrifos. We would also like to discuss with EPA how the rationale for the Final Rule relates to the decision whether to allow the continued registration of chlorpyrifos products under FIFRA.

Sincerely,
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This letter was prepared by Robert Perlis and William Jordan.

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