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# Frequent Questions about the Chlorpyrifos 2021 Final Rule

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### 13. Is my product subject to the tolerance revocation?

### 1. How did the Agency come to the conclusion to revoke all tolerances?

The final rule was issued in response to the Ninth Circuit Court of Appeals' order directing EPA to issue a final rule in response to the 2007 petition filed by Pesticide Action Network North America and the Natural Resources Defense Council. In issuing the final rule, EPA found that it could not determine that there is a reasonable certainty of no harm from aggregate exposure, including food, drinking water, and residential exposure, to chlorpyrifos, based on currently available data and taking into consideration all currently registered uses for chlorpyrifos.

The Agency's evaluation indicated that currently registered uses of chlorpyrifos result in exposures exceeding the safe levels of exposure, and thus have the potential to result in adverse effects. The <u>final ruleExit EPA's website</u> revokes tolerances and will reduce risks to our most vulnerable populations, including children, by reducing chlorpyrifos exposure via food and drinking water.

### 2. What is the role of epidemiology data in this decision for chlorpyrifos?

EPA sought to address the potential neurodevelopmental effects associated with chlorpyrifos exposure over the past decade, but these efforts ultimately concluded with the lack of a suitable regulatory endpoint based on these potential effects. While EPA sought to verify the conclusions of the epidemiology studies conducted by Columbia University, it has been unable to confirm the findings of the Columbia Center for Children's Environmental Health studies or conduct alternative statistical analyses to evaluate the findings. The inhibition of acetylcholinesterase (AChE) leading to cholinergic neurotoxicity and the potential for effects on the developing brain (i.e., neurodevelopmental effects) are the most sensitive effects seen in the available data.

### 3. How does this decision impact current crops that were harvested during Fall 2021, on which chlorpyrifos was used?

The timing of application will determine whether food and animal feed treated with chlorpyrifos is adulterated. Before the tolerances expired on Feb. 28, 2022, chlorpyrifos could have been used on food and animal feed commodities in accordance with label directions and the existing tolerances. These conditions are described in section 408(I)(5) of the Federal Food, Drug, and Cosmetic ActExit EPA's website (FFDCA) and allow that residues of chlorpyrifos in or on the food and/or animal feed after the tolerances expired would not render the food or animal feed adulterated, as long as those conditions are met. After the tolerances expired on Feb. 28, 2022, new applications of chlorpyrifos will render any food or animal feed treated as adulterated and ineligible to be distributed in interstate commerce. Food and animal feed already in the channels of trade that were treated prior to the expiration of the tolerances would be governed by section 408(I)(5) of the FFDCA, as described above. On Feb. 9, 2022, the Food and Drug Administration (FDA) released specific guidance, which is consistent with the channels of trade provision, to address questions related to treated commodities with chlorpyrifos residues, including imported foods. View the FDA

guidance for more informationExit EPA's website.

### 4. What is the impact of the final rule on Chlorpyrifos registration review?

The final rule revoked all tolerances and EPA is in the process of cancelling food uses due to the lack of tolerances. Thus, EPA intends to evaluate the non-agricultural, non-food uses as part of the ongoing registration review for chlorpyrifos.

On Jan. 18, 2017, as part of the registration review process and to meet its obligation under Section 7 of the Endangered Species Act (ESA), EPA issued nationwide biological evaluations (BEs) for chlorpyrifos, diazinon, and malathion to assess risks to threatened and endangered (listed) species from registered uses of these organophosphate pesticides. EPA also initiated formal consultation with the U.S. Fish and Wildlife Service (FWS) and has reinitiated formal consultation with the National Marine Fisheries Service (NMFS) (the Services) based on the BE conclusions that these pesticides may affect certain listed species and/or their designated critical habitats. EPA continues to be in consultation with the Services on chlorpyrifos. On Mar. 2, 2022, EPA posted the NMFS draft biological opinion (BiOp) for chlorpyrifos, diazinon and malathion for a 60-day public comment period. Public comments on NMFS's draft revised BiOp will be accepted for 60 days in docket EPA-HQ-OPP-2002-0172Exit EPA's website at www.regulations.govExit EPA's website.

#### 5. What about imported food and animal feed treated with chlorpyrifos?

Under 21 U.S.C. 346a(I)(5) (also referred to as the "channels of trade provision"), chlorpyrifos residues on food, which is defined in the FFDCA to include animal feed, must have resulted from lawful application in order for the food to be legally distributed in interstate commerce. This means that chlorpyrifos must have been applied in accordance with label directions prior to the expiration date of the tolerances, i.e., prior to Feb. 28, 2022, and residues from that application do not exceed the tolerance levels. FDA stated in its channels of trade policy that it intends to subject the importation of any food bearing a residue (within the former tolerance) of a pesticide chemical for which a tolerance has been revoked, suspended, or modified to the same enforcement approach as for a domestic food. For information on FDA's channels of trade policy, please refer to FDA's "Guidance for Industry: Channels of Trade Policy for Commodities With Residues of Pesticide Chemicals, for Which Tolerances Have Been Revoked, Suspended, or Modified by the Environmental Protection Agency Pursuant to Dietary Risk Considerations". In addition, FDA released specific guidance, which is consistent with the channels of trade provision, to address questions related to treated commodities with chlorpyrifos residues, including imported foods. View the FDA guidance for more informationExit EPA's website.

<u>Information on contacting FDAExit EPA's website</u>.

### 6. Can chlorpyrifos still be used on crops if they are exported and not used for domestic food or feed consumption?

Unless cancelled, chlorpyrifos can still be used on food and animal feed crops intended solely for export, as long as certain conditions are met: use of the pesticide "accords to the specifications of the foreign purchaser, is not in conflict with the laws of the country to which it is intended for export, is labeled on the

outside of the shipping package that it is intended for export, and is not sold or offered for sale in domestic commerce" (21 USC 381(e)(1)Exit EPA's website). For additional information on exported crops, please contact the Center for Food Safety and Applied Nutrition at FDA (<u>CFSANTradepress@fda.hhs.gov</u>).

### 7. How does this rule impact commodities that have food, animal feed and non-food products derived from those commodities? Are there any non-crop uses that are impacted by this decision?

The revocation of tolerances impacts any food and animal feed products derived from crops that produce both food and non-food commodities. It is the timing of application that determines whether food and animal feed treated with chlorpyrifos is adulterated. Until the tolerances expired on Feb. 28, 2022, chlorpyrifos could have been used on food and animal feed commodities in accordance with label directions and the existing tolerances. These conditions are described in section 408(I)(5) of the FFDCA (21 U.S.C. 346a(I) (5)), and allow that residues of chlorpyrifos in or on the food and animal feed after the tolerances expire would not render the food adulterated, as long as those conditions are met. The full text of the statutory provision can be found in section 408(I)(5) of the FFDCA (21 U.S.C. 346a(I)(5))Exit EPA's website

Now that the tolerances have expired, new applications of chlorpyrifos will render any food or animal feed treated adulterated and unable to be distributed in interstate commerce. Food and animal feed in the channels of trade that was treated prior to the expiration of the tolerances would be governed by section 408(I)(5) of the FFDCA, as described above. FDA released specific guidance, which is consistent with the channels of trade provision, to address human food commodities with chlorpyrifos residues, including imported foods. View the FDA guidance for more information Exit EPA's website. Additionally, tolerances are only required for food and animal feed products; if the commodity produced from a crop is not a food or animal feed, then the lack of a tolerance does not matter. The following are examples to help inform some situations.

- a. Applications of chlorpyrifos to or around fruit/nut trees may be considered a non-food use provided applications are made to non-bearing trees (i.e., trees without fruit present at the time of application and that will not bear fruit within one year). If growers are in possession of chlorpyrifos products labeled for application to fruit/nut trees, growers may apply those products consistent with the labeling after Feb. 28, 2022, in the following manner: application is permitted fruit and nut trees that are in their first year of planting (or grafted onto existing roots) and will not bear any fruit or nuts within one year, and to any non-bearing fruit trees. Chlorpyrifos products used in the way described above will still be consistent with the label directions. If the label contains food or animal feed uses, movement of the chlorpyrifos pesticide product for disposal would be considered unlawful unless covered by a cancelation order. Please refer to Question 12 for more information on transport and disposal.
- Cattle ear tags containing chlorpyrifos that are currently registered chlorpyrifos products are considered a food use because use results in

residues in or on cattle and does not contain any restrictions to prohibit residues in livestock commodities. However, if registrants submit applications on beef and non-lactating dairy cattle, and on cattle in mating and cow-calf operations, as long as the animals are not offered slaughter within one year of tag removal, such use would not result in residues in or on livestock commodities. Once such labels are approved and products are available with the new labels, operators using those newly labeled products should maintain records to capture dates of ear tag removal and when animals are sent to slaughter.

- c. The currently registered seed treatment uses are considered food and/or animal feed uses based on the available data. In order for EPA to determine whether any seed treatment uses might be considered a food, animal feed or non-food use, a <u>Pesticide Registration Improvement Extension Act (PRIA)</u> application with sufficient supporting data would need to be submitted for review by the Agency. Please refer to Question 8 for additional information on treated seed.
- d. Crops grown for seed: There are Special Local Needs, also known as 24(c) registrations, in some states that bear language which could be considered non-food/non-feed. EPA considers "crops grown for seed" to be non-food/non-feed uses when covered by the following label restrictions:
  - a. There are extensive restrictions on the label for the pesticide treating the seed, including that the seed harvested from the crop bears labels with a prohibition against human consumption or use as an animal feed.
  - b. In addition, the label for the pesticide treating the seed states the "no portion of this seed crop may be used or distributed for food or feed for 1 year (365 days) after the last application of this product"; this includes all portions of the crop (e.g., forage, hay, meal, roots) and extends to grazing of animals in the fields.

For labels without these restrictions, registrants would need to submit, and EPA would need to approve, applications to amend the labels. Then the registrant could relabel the products, and use consistent with those new labels would be permissible.

a. By products of food and feed grown for non-food uses, such as corn for ethanol, may contain chlorpyrifos residues and, therefore, cannot be used in a way that would result in human dietary exposure. Examples of prohibited uses for byproducts of crops treated with chlorpyrifos include use as a fertilizer or feed for livestock.

#### 8. What should be done with treated seed?

Currently registered seed treatment uses are considered food uses, meaning that they are subject to the tolerance rule and the Feb. 28, 2022 tolerance expiration date. Crops grown from treated seeds will also need to be consistent with FDA's channels of trade guidance Exit EPA's website. FDA's guidance specifies how long commodities can be in the channels of trade with chlorpyrifos residues after the tolerance expiration, so growers can make an informed decision regarding planting. If the seeds were lawfully treated before Feb. 28, 2022, growers can still plant the seeds. If the crops are harvested after the showing date, and FDA finds the crops with residues that comply with previous tolerances, the responsible party of the crops will need to submit records/documentation to FDA to demonstrate that the chlorpyrifos residues are present as a result of lawful application. For specific questions, please contact the Center for Food Safety and Applied Nutrition at FDA (CFSANTradepress@fda.hhs.gov).

### 9. If there are going to be label changes, when will they occur?

Any registrant, including those who hold registrations of chlorpyrifos, can cancel the registration of a pesticide product or terminate a use at any time by voluntarily submitting a request to the Agency. The Agency requested that registrants submit a letter formally expressing their intention to submit registration amendments to remove food and animal feed uses from product labels or submit a voluntary cancellation for products where all uses are subject to the tolerance revocation by Mar. 30, 2022. The Agency will work as quickly as possible to process label amendments and voluntary cancellations. On <a href="Dec. 14">Dec. 14</a>, 2022, the Agency issued a Notice of Intent to Cancel (NOIC)under the Federal Insecticide, Fungicide, and Rodenticide Act to initiate the cancellation process for registrations bearing labeling for use on food or animal feed for which requests to voluntarily cancel or terminate uses or for which label amendments were not submitted. The NOIC is available in docket <a href="EPA-HQ-OPP-2022-0417Exit EPA's website">EPA's website</a> at <a href="www.regulations.govExit EPA's website">www.regulations.govExit EPA's website</a>. When EPA issues an NOIC, it will be published in the Federal Register. For more information on the NOIC process, visit EPA's website Exit EPA's website.

### 10. What is the impact of this rule on existing stocks?

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 <u>tolerance ruleExit EPA's website</u> issued on Aug. 30, 2021, did not prohibit sale and distribution of registered pesticide products. However, since the tolerances expired on Feb. 28, 2022, chlorpyrifos products labeled for use on food and animal feed crops are now considered misbranded; therefore, it is a violation of FIFRA to sell and distribute those products.

A registrant, including those of chlorpyrifos, can cancel its registration of a pesticide product or terminate a use at any time by <u>voluntarily submitting a request</u> to the Agency. EPA will cancel chlorpyrifos products or terminate registered food and animal feed uses of chlorpyrifos associated with the revoked tolerances under FIFRA, as it receives and processes requests from the registrants to cancel products/registrations.

Generally, those cancellation orders will not impact non-food 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 will need to be amended to remove any food and animal feed uses that are terminated.

On Apr. 28, 2022, EPA published in the Federal Register a notice that it had received requests from registrants seeking to voluntarily cancel 16 chlorpyrifos products (87 FR 25256Exit EPA's website) (FRL-9723-01-OCSPP). The public comment period for that notice closed on May 31, 2022. EPA responded to the public comments in the Cancellation Order for Certain Chlorpyrifos RegistrationsExit EPA's website, which was published in the Federal Register on Aug. 31, 2022 (87 FR 53471) (FRL-10138-01-OCSPP). That order contained terms for existing stocks of chlorpyrifos, i.e., those products that were in the United States and were packaged, labeled, and released for shipment as of the date of that cancellation order. As EPA issues other cancellation orders addressing other chlorpyrifos registered products, those orders will also contain existing stocks terms to address the disposition of those products.

### 11. What were EPA's responses to objections on the final rule?

Consistent with FFDCA section 408(g), 21 U.S.C. 346a(g), EPA provided an opportunity for any person to file an objection to any aspect of the final rule and request a hearing on those objections. The deadline for all objections and hearing requests was Oct. 29, 2021.

On Feb. 28, 2022, EPA published its determination in the Federal Register with respect to each of the objections and hearing requests. The response to the objections for chlorpyrifos is available in docket <u>EPA-HQ-OPP-2021-0523Exit EPA's website</u> at <u>www.regulations.govExit EPA's website</u>.

## 12. What should applicators and distributors do if they have chlorpyrifos products for use on food and animal feed now that the tolerances have expired?

All tolerances for chlorpyrifos expired on Feb. 28, 2022. These tolerances were established in 40 CFR §180.342Exit EPA's website ("Chlorpyrifos; tolerances for residues") as required by 21 U.S.C. § 346aExit EPA's website ("Tolerances and exemptions for pesticide chemical residues").

- Use. Anyone in possession of chlorpyrifos products for use on food and animal feed should discontinue use on food and animal feed. If the product's label allows for non-food uses, you may continue to use the product for those non-food purposes consistent with the label.
- Sale and Distribution. Products with food and animal feed uses (including products with both food, animal feed and non-food uses) on the label are currently misbranded and may be not sold or distributed. Registrants must submit label amendments to reflect the appropriate subset of uses that are still permitted.
- Storage. Store chlorpyrifos products until there is an opportunity for

appropriate disposal. Details on proper storage can be found using the following links:

- https://www.epa.gov/safepestcontrol/storing-pesticides-safely
- https://www.epa.gov/pesticide-worker-safety/requirements-pesticidestorage
- Transport and Disposal. FIFRA prohibits the distribution of misbranded pesticides, without any exception for transfer for the purposes of disposal (7 U.S.C. § 136j(a)(1)(E)). EPA's regulations allow for the transfer of pesticides that are unregistered, cancelled, or suspended solely for the purposes of disposal, as long as certain conditions are met. (40 CFR 152.30(f)). For chlorpyrifos products that are being cancelled, EPA expects to address the movement of products for disposal purposes in cancellation orders. Products that are not cancelled, a Stop Sale, Use, or Removal Order (SSURO) could allow for transport. Until chlorpyrifos products are cancelled, they cannot be transported for disposal with limited exceptions (e.g., the Agency can issue a Stop Sale, Use, or Removal Order (SSURO) if it is necessary to allow for lawful transport of product prior to cancellation).
  - Until chlorpyrifos products are cancelled, they cannot be transported for disposal with limited exceptions (e.g., the Agency can issue a Stop Sale, Use, or Removal Order (SSURO) if it is necessary to allow for lawful transport of product prior to cancellation).
  - After cancellation, return programs are expected to be available for some chlorpyrifos products. Instructions for return programs and transport for disposal will be available in upcoming final cancellation orders.
    - The Agency will provide updates regarding registrant return programs on this website and to state lead agencies.
    - For products not subject to a registrant return program, appropriately dispose of these products as specified by product labels and your state. For contact information, please see <a href="https://tpsalliance.org/resources/state-disposal-map/ExitEPA's website">https://tpsalliance.org/resources/state-disposal-map/ExitEPA's website</a>

### 13. Is my product subject to the tolerance revocation?

- The tolerance revocation impacts the following uses:
  - Terrestrial Food Crops and Greenhouse Food Crops including:
     Alfalfa, apple, asparagus, banana, bean (snap, lima), beet (sugar, table, including crops grown for seed), blueberry, brassica (cole) leafy

vegetables (bok choy, broccoli rabe, broccoli, Brussels sprout, cabbage, Chinese cabbage, cauliflower, collard, kale, kohlrabi), caneberry, cherimoya, cherry (sour, sweet), citrus (lemon, orange, grapefruit and citrus, other) citrus orchard floor, corn (field, sweet, including crops grown for seed), cotton, cranberry, cucumber, date, feijoa, fig, grape, kiwifruit, leek, legume vegetables, mint, nectarine, onion (dry bulb), pea, peach, peanut, pear, pepper, plum, prune, pumpkin, radish (including crops grown for seed), rutabaga, sapote, seed and pod vegetables, sorghum (grain, milo), soybean, strawberry, sugarcane, sunflower, sweet potato, tree nuts (almond, filbert, pecan, walnut, other), turnip, wheat, and seed treatment.

- Food handling establishments, including food processing and food manufacturing establishments, were included in the former tolerances for chlorpyrifos under 40 CFR 180.342. Since all tolerances were revoked, use on these sites is no longer permitted.
- Commercial Livestock Uses: Cattle ear tags, poultry houses, turkey barns, swine barns, dairy barns/areas, hog barns, empty chicken houses, calf hutches, calving pens, milking parlors, and milk rooms
- The tolerance revocation does not impact the following uses:
  - Ornamentals: Commercial production only (flowers, shrubs, evergreens, vines, shade, and flowering trees in nurseries or greenhouses only); Christmas trees; forest tree nurseries; commercial sod farms.
  - Applications of chlorpyrifos to or around fruit and nut trees (almonds, citrus, filbert, apple, cherry, nectarine, peach, pear, plum, prune) are considered a non-food use provided applications are made to non-bearing trees (i.e., trees without fruit present at the time of application and that will not bear fruit within one year). Refer to Question 7a for more information on non-bearing fruit and nut trees.
  - Crops grown for seed (including grass): Food, feed, and non-food crops grown for seed are considered to be non-food/non-feed uses when covered by the label restrictions described in Question 7d.
  - Forest trees: Plantations, forest seed orchards, felled trees, cut stumps.
  - Tobacco
  - Commercial indoor non-residential: Warehouses, ship holds, railroad boxcars, industrial plants, or containerized baits.
  - Outdoor residential public health uses: fire ant mount (individual), mosquito control.

- Outdoor non-residential: Golf courses, road medians, industrial plants, fence posts, utility poles, railroad ties, landscape timbers, logs, poles, and posts.
- o Indoor residential: Ant and roach bait (containerized).
- Commercial outdoor: Underground utility cables and conduits; turf and ornamentals in road medians and industrial plant sites; interior treatment of warehouses, railroad boxcars, industrial plants, and manufacturing plants.
- Turf: Golf course turf, turf in road medians, and turf in industrial plant sites.
- Public health: USDA quarantine (i.e., soil treatment of containerized plants) in nurseries and greenhouses; fire ant mounds (individual mounds), and mosquito control.

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