OBJECTIONS OF THE STATES OF NEW YORK, WASHINGTON, CALIFORNIA, MASSACHUSETTS, MAINE, MARYLAND, AND VERMONT TO EPA'S MARCH 29, 2017 ORDER DENYING PETITION TO REVOKE TOLERANCES FOR CHLORPYRIFOS AND LEAVING TOLERANCES IN EFFECT

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EPA-HQ-OPP-1005
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Introduction

The States of New York, Washington, California, Massachusetts, Maine, Maryland, and Vermont submit these legal objections to the EPA Administrator's March 29, 2017 order and request immediate agency action to vacate the order and to take final action on EPA's proposed rule to revoke tolerances for chlorpyrifos. The States submit these objections after years of delayed action on the part of EPA with respect to chlorpyrifos tolerances.

In response to a 2007 administrative petition and subsequent litigation filed by the Natural Resources Defense Council (NRDC) and the Pesticide Action Network North America (PANNA), in November 2015, EPA issued a notice of proposed rulemaking to revoke all chlorpyrifos food tolerances. The proposed rule stated that EPA could not find that human exposures to chlorpyrifos met the safety standard under the Federal Food, Drug and Cosmetic Act (FFDCA). The administrative record on which EPA relied showed the lack of safety associated with the continued use of chlropyrifos on food because of its adverse neurodevelopmental effects, particularly in children.

In a second proposed rulemaking in November 2016, EPA addressed certain issues presented by the agency's Science Advisory Panel, but reiterated that chlorpyrifos did not meet the FFDCA safety standard. In that proposed rulemaking, EPA noted that no party had proposed mitigation measures that would allow even some tolerances to be left in effect.

On March 29, 2017, the Administrator abruptly reversed EPA's position on finalizing the proposed rulemaking and issued an order, which denied the 2007 NRDC/PANNA petition to revoke all chlopryrifos tolerances, and left in effect the existing tolerances. The Administrator's order did not make the statutorily

required finding under the FFDCA that those tolerances are "safe," however. 21 U.S.C. § 346a(b)(2)(A).

The order is not authorized by the FFDCA and is an improper exercise of the Administrator's authority because EPA failed to make the safety finding required by law in order to leave pesticide tolerances in effect. Moreover, the Administrator's order did not comply with two orders of the United States Court of Appeals for the Ninth Circuit, which directed EPA to take final action on the proposed tolerance revocation rule as well as the NRDC/PANNA petition.

As further detailed below, the States object to the order as unlawful under the FFDCA and request a response to their objections and vacatur of the order within 60 days of the date of these objections. The States further request that EPA comply with the Ninth Circuit's orders and issue a final rule on the proposed revocation of chlorpyrifos tolerances within 60 days of the date of these objections.

The States' Interest

Chlorpyrifos is an active ingredient in numerous EPA registered pesticide products approved for use on more than 80 foods. EPA's March 29, 2017 order leaves in effect tolerances on food consumed by the citizens of the States without the finding of safety required by law. Consumers nationwide ingest foods that are grown throughout the United States and the world, many of which contain chlorpyrifos residues that have not been found by EPA to be safe. EPA's decision to deny the petition and leave in effect chlorpyrifos tolerances has resulted in the continued sale and consumption of food commodities that contain chlorpyrifos residues not found to be safe, as required by FFDCA Section 408(b), 21 U.S.C. § 346a(b)(2)(A). Accordingly, the citizens of the States are being exposed to chlorpyrifos residue levels on foods that have not been demonstrated or currently found to be safe.

Action by the States to curtail human exposure would not be fully effective, given the national markets for foods. The States have a strong interest in assuring appropriate federal regulatory action, including a final decision by the Administrator about whether existing chlorpyrifos food tolerances are safe and may remain in effect. Under the FFDCA, it is EPA's legal responsibility to protect Americans from unsafe residues on food, and particularly to protect infants and children against potential neuro-developmental and other adverse health effects. The Administrator's order to leave tolerances in effect that EPA has not found to

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be safe has potential human health impacts and is therefore directly contrary to the States' interest of protecting the health and welfare of their citizens.[1]

Background

Chlorpyrifos, which was first registered in 1965, is now one of the most widely used pesticides in the United States. EPA's regulations identify more than 80 tolerances for use on food crops, including foods consumed by infants and children such as apples, strawberries, bananas, pears, peaches, nectarines and cherries. 40 C.F.R. § 180.342. It has been the subject of regulatory review for decades because of its well-documented harmful human health effects. Chlorpyrifos residues have been documented repeatedly in numerous baby foods and juices. *See* EPA 2014 Dietary Exposure Analysis.[2] EPA has established by regulation acceptable chlorpyrifos residue levels, known as "tolerances." 40 C.F.R. § 180.342.

Set forth below is a brief summary of the administrative and judicial actions leading up to the Administrator's March 29, 2017 order:

2007 NRDC/PANNA Administrative and Judicial Petitions. In 2007, NRDC and PANNA filed an administrative petition with EPA requesting revocation of all chlorpyrifos food tolerances pursuant to 21 U.S.C. § 346a(d). EPA-HQ-OPP-2007-1005; 72 Fed Reg. 58,845 (Oct. 17, 2007). For seven years, EPA failed to act on the petition. Consequently, NRDC and PANNA filed a petition in the Ninth Circuit Court of Appeals seeking a writ of mandamus to

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[1] New York has been a party to prior administrative proceedings involving chlorpyrifos. In December 1999, the NYOAG filed comments with EPA and highlighted the - then well-documented potential adverse human health effects associated with exposure. EPA-HQ-OPP-34203. The NYOAG requested that *all* uses be banned, both on food crops and as a termiticide. In 2000, EPA and the industry agreed to the voluntary cancellation of most termiticide uses. EPA left its use on food crops unaffected. In January 2002, the NYOAG filed a second set of comments with EPA [EPA-HQ-OPP-34203; 66 Fed. Reg. 57,073 (Nov. 14, 2001)], and stated that chlorpyrifos food tolerances "are not safe and will result in unreasonable adverse impacts on human health and the environment," within the meaning of the FFDCA, particularly to vulnerable populations such as infants and children. Washington State has also submitted comments to EPA discussing health impacts and avenues for limited chlorpyrifos use. *See, e.g.*, EPA-HQ-OPP-2008-0850 (May 8, 2015 letter from Washington State Department of Health); EPA-HQ-OPP-2015-0653-0370 (January 28, 2016 comment from Washington State Department of Agriculture).

[2] *See also* U.S. Department of Agriculture Pesticide Data Program Reports, 1994 to 2015.

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compel EPA's decision on the merits of the administrative petition. *PANNA and NRDC v. USEPA,* Case No. 14-72794 (Dkt No. 1).[3]

The Ninth Circuit's August 10, 2015 Writ of Mandamus. On August 10, 2015, the Ninth Circuit issued an order granting a writ of mandamus and directing EPA "to issue either a proposed or final revocation rule or a full and final response to the administrative petition" by October 2015. *PANNA and NRDC v. USEPA,* 798 F. 3d 809, 814 (9th Cir. 2015). The Court found the agency's inaction "egregious" and its delay unreasonable because no action had been taken nine years after the petition was filed. The Court recounted the urgency associated with chlorpyrifos, namely, significant human health concerns:

> Although EPA determined that chlorpyrifos was "safe" in 2006, it has backtracked significantly from that pronouncement over the last several years. EPA recently imposed new labeling requirements on the chemical, and in its latest status report, EPA reported that chlorpyrifos poses such a significant threat to water supplies [and] that a nationwide ban on the pesticide may be justified. We do not take this representation lightly. Yet EPA offers no acceptable justification for the considerable human health interests prejudiced by the delay. In view of EPA's own assessment of the dangers to human health posed by this pesticide, we have little difficulty concluding it should be compelled to act quickly to resolve the administrative petition.

798 F.3d at 814.

EPA's November 6, 2015 Proposed Rulemaking. In November 2015, EPA issued a notice of proposed rulemaking to revoke all tolerances for chlorpyrifos because the agency was "unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard of section 408(b)(2)" of the FFDCA. 80 Fed. Reg. 69,080 (Nov. 6, 2015). EPA specifically found that "the consistency of finding neurodevelopmental effects is striking" in the scientific literature. 80 Fed. Reg. at 69,090. In reaching its determination to revoke the tolerances, EPA looked at both food and drinking water exposures. EPA requested

[3] That Ninth Circuit petition was preceded by a 2012 petition for mandamus by the same groups, which the Ninth Circuit dismissed because it found that EPA would act on chlorpyrifos "on a concrete timeline." 532 F. App'x 649, 651-52 (9th Cir. 2013).

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public comment on its proposed rule and on the human health risk assessment and drinking water risk assessment supporting the action.

The Ninth Circuit's December 10, 2015 Order. In a December 10, 2015 order, the Ninth Circuit directed EPA "to take final action by December 30, 2016 on its proposed revocation rule and its final response" to the NRDC/PANNA 2007 administrative petition to revoke tolerances for chlropyrifos (Dkt Entry 29, p. 2). The Court also directed EPA to file status reports to advise the Court and the parties of the agency's efforts to comply with the deadline for final agency action on both the tolerance revocation rule and the NRDC/PANNA petition.

The Ninth Circuit's August 12, 2016 Order. Ultimately, EPA moved for a six-month extension of the Court's December 30, 2016 deadline, citing "extraordinary circumstances." In an August 12, 2016 order, the Court denied EPA's motion for a six-month extension to take final action on the revocation rule and the NRDC/PANNA petition. Instead, the Court directed EPA "to take final action" on the revocation rule and on the NRDC/PANNA administrative petition by March 31, 2017 (Dkt Entry 51, p. 4).

EPA's November 17, 2016 Proposed Rulemaking. In November 2016, EPA issued a second notice of proposed rulemaking, reopening the comment period and issuing revised risk assessments.[4] 81 Fed. Reg. 81,049 (Nov. 17, 2016). EPA addressed certain recommendations of the agency's Science Advisory Panel but continued to assert that its analysis of chlorpyrifos "continues to indicate that the risk from potential aggregate exposure does not meet the FFDCA safety standard." *Id.* at 81,050. Notably, the proposed rule stated that "EPA can only retain chlorpyrifos tolerances if it is able to conclude that such tolerances are safe." *Id.* EPA further stated that it had not received any proposals for mitigation measures that the chlorpyrifos registrants would be willing to undertake to allow EPA to retain *any* tolerances. *Id.*

The EPA Administrator's March 29, 2017 Order. On March 29, 2017, Administrator Scott Pruitt issued an order denying the 2007 NRDC/PANNA petition to revoke tolerances. 82 Fed. Reg. 16,581 (March 29, 2017). EPA summarized its position as follows:

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[4] *Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review (2016) and Chlorpyrifos Registration Review Drinking Water Assessment (2016).*

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> EPA has concluded that despite several years of study, the science addressing neurodevelopmental effects remains unresolved and that further evaluation of the science during the remaining time for completion of registration review [by October 2022] is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposure to chlorpyrifos. EPA has therefore concluded that it will not complete the human health portion of the registration review or any associated tolerance revocation of chlorpyrifos without first attempting to come to a clearer scientific resolution on those issues.

Id. at 16,583.

The order had the effect of leaving chlorpyrifos food tolerances in place that the Administrator has not determined to be safe. Moreover, these tolerances would remain in effect until at least October 2022, the deadline Congress has set for EPA to complete registration review of chlorpyrifos and other pesticides. *See* 7 U.S.C. § 136a(g)(1)(A)(iii). The order initiated a new administrative process by providing interested parties with an opportunity to file objections to the order and request an evidentiary hearing under the procedures set forth in 40 C.F.R. Part 178. 21 U.S.C. § 136a(g)(2). The order did not address EPA's prior two proposed rulemakings to revoke all tolerances, which the agency had issued in November 2015 and November 2016.

Statutory and Regulatory Framework and Analysis

FFDCA Section 408. The Food Quality Protection Act of 1996 (FQPA) amended both the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the FFDCA and it was passed for the purpose of assuring that pesticide residues on foods are "safe" when considering aggregate and cumulative human exposure scenarios (via food, water, and other human exposures).[5] FFDCA Section 408a(b) identifies the safety standard that must be met and states that EPA may leave in effect a tolerance for a pesticide residue on food *only if* the EPA Administrator determines that the tolerance is safe:

[5] 21 U.S.C. § 346a(q) ("[t]he Administrator shall review tolerances and exemptions for pesticide chemical residues in effect … as expeditiously as practicable…."

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> Standard. The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on food *only if* the Administrator determines that the tolerance is safe. The Administrator *shall modify or revoke a tolerance if the Administrator determines it is not safe.*

21 U.S.C § 346a(b)(2)(A)(i) (emphasis added). The Administrator's determination of safety means that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information. 21 U.S.C. § 346a(b)(2)(A)(ii).

The first sentence of Section 408(b)(2)(A)(ii) prohibits the Administrator from leaving a pesticide tolerance in effect without determining that the tolerance is safe. The Administrator's March 29, 2017 order left tolerances for chlorpyrifos in place indefinitely, but contains no finding of safety. Congress gave the Administrator the discretion to leave a tolerance in effect, but required EPA to determine that the tolerances are safe in order to do so. This safety standard applies whether the Administrator acts in response to a petition, as here, or as part of the reregistration process under FIFRA. Furthermore, the second sentence of Section 408(b) requires the Administrator to modify or revoke a tolerance if he finds that it is not safe. There is no authority given to the Administrator to leave a tolerance in effect in the absence of a finding of safety.[6]

Thus, the FFDCA does not authorize the position EPA has taken here. EPA has not found chlropyrifos tolerances to be safe, but nevertheless has left the tolerances in effect for the foreseeable future. EPA in its proposed rulemakings stated unequivocally that it cannot find the tolerances to be safe. Although EPA has not issued a *final* rule indicating that chlorpyrifos tolerances are not safe, its November 2015 and November 2016 notices of proposed rulemaking indicate precisely that. And despite the unequivocal statements in those notices, the Administrator's March 29, 2017 order is a decision to leave existing chlorpyrifos tolerances in effect, but without the required finding of safety. That action is not lawful under Section 408(b)(2)(A)(i), 21 U.S.C. (b)(2)(A)(i).

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[6] Section 408(b) further provides that a tolerance may be left in effect only if use "protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue," or the pesticide's continued use avoids "a significant disruption in domestic production of an adequate, wholesome, and economical food supply." 21 U.S.C. § 346a(b)(2)(B)(ii), (iii). Nothing in the Administrator's order addresses either of these circumstances.

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Procedure Under FFDCA Section 408(d). FFDCA Section 408(d)(1) provides that any person may file a petition with EPA "establishing, modifying or revoking a tolerance." 21 U.S.C. 346a(d)(1). Section 408(d)(4) provides that upon due consideration of a petition and other available information, EPA shall (1) issue a final regulation establishing, modifying or revoking a tolerance without further notice and public comment; (2) issue a proposed rulemaking; or (3) issue an order denying a petition to revoke a tolerance. 21 U.S.C. 346a(d)(4)(A)(i) - (iii).

Once EPA issues an order and acts on a petition, interested parties may file objections to the order within 60 days and specify "reasonable grounds" for the objections. 21 U.S.C. § 346a(g)(2)(A). Interested parties also may request a public evidentiary hearing on the objections. 21 U.S.C. § 346a(g)(2)(B). The Administrator is empowered to hold a hearing but only if one "is necessary to receive factual evidence relevant to material issues of fact raised by the objections." 21 U.S.C. § 346a(g)(2)(B).

In any event, "*[a]s soon as practicable* after receiving the arguments of the parties, the Administrator shall issue an order stating the action taken upon each such objection and setting forth any revision to the regulation or prior order...." 21 U.S.C. § 346a(g)(2)(C) (emphasis added). The term "as soon as practicable" is intended to impose a reasonable time frame in which the Administrator shall rule on the objections to the order.

Objections

1. The Administrator Does Not Have the Authority Under FFDCA Section 408(b) to Issue an Order Leaving Tolerances in Effect Without Finding that the Tolerances Are Safe.

The FFDCA safety standard for pesticide food tolerances governs the Administrator's actions here. 21 U.S.C. § 346a(b). The Administrator may leave tolerances in effect only if he determines that the tolerances are safe, meaning that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures (e.g., drinking water exposure, occupational exposure, etc.) for which there is reliable information. 21 U.S.C. § 346a(b)(2)(A). The Administrator does not have the authority to leave a tolerance in place in the absence of a safety finding. Because the Administrator did not issue a safety finding to support the March 29, 2017 order, it is unlawful and must be vacated.

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The Administrator's order also conflates EPA's registration authority under FIFRA with the safety standard that must be met under the FFDCA when the Administrator leaves tolerances in effect. The FFDCA safety standard applies regardless of whether the context is registration review of a pesticide or a petition for revocation of a tolerance. 21 U.S.C. § 346a(b)(2).

The States disagree with EPA's assessment that leaving tolerances in effect by denying the NRDC/PANNA petition "is wholly consistent with governing law." (Order, p. 61). EPA may not leave tolerances in effect by denying an FFDCA petition without making a finding that the tolerances are safe. 21 U.S.C. § 346a(b)(2)(A). Nothing in the FFDCA allows EPA to ignore the necessary safety finding by deferring that issue for years until registration review is complete.

Moreover, EPA's suggestion that the petition seeks to "reorder scheduling decisions regarding FIFRA registration review process that Congress has vested in the Administrator" (Order, p. 61) misses the point of the FFDCA safety standard. Nothing in the FFDCA authorizes EPA to leave tolerances in effect and defer the safety finding until registration review. The FIFRA coordination provision in FFDCA 408(l)(1) does not override the required finding of safety when tolerances are left in effect in response to a petition.

EPA's order also incorrectly states the applicable legal standard set forth in FFDCA Section 408(b) for leaving a tolerance in effect. EPA states that the "basis for seeking revocation of a tolerance is a showing that the pesticide is not 'safe.'" (Order pp. 45, 51). The FFDCA expressly provides that the Administrator has the authority to establish or leave a tolerance in place *only if* he finds the tolerance safe. 21 U.S.C. § 346a(b)(2)(A). There is no requirement that a petitioning party prove that a pesticide is not safe. Indeed, it is the registrant's burden to prove safety. *See* 7 U.S.C. § 136a(c). The issue is whether the Administrator can leave a tolerance in effect through the denial of a petition to revoke tolerances in the absence of a finding of safety. The Administrator is not given that authority in the FFDCA.

The Administrator's March 29, 2017 order is inconsistent with the FFDCA's requirement that a tolerance be found safe if left in effect because it makes no such safety finding.

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2. *The Administrator's Order is a Violation of the Ninth Circuit's Orders Requiring EPA to Take Final Action on Its Proposed Tolerance Revocation Rule.*

EPA's March 29, 2017 order is invalid because EPA did not comply with two Ninth Circuit orders directing it to take final action on its proposed tolerance revocation rule.[7] In a December 10, 2015 order, the Ninth Circuit directed EPA "to take *final* action by December 30, 2016 on its proposed revocation rule...." (Dkt. Entry 29, p. 2) (emphasis added). Then, in an August 12, 2016 order, the Ninth Circuit denied EPA's motion for a six-month extension to take final action on its proposed tolerance revocation rule, and again directed EPA "to take final action by March 31, 2017" (Dkt. Entry 51, p. 4). The August 12, 2016 order reflects the Ninth Circuit's obvious frustration with the agency's ongoing delay in taking final action:

> The "extraordinary circumstances" claimed this time—that EPA issued its proposed rule before completing two studies that may bear on the Agency's final rule—is another variation on a theme "of partial reports, missed deadlines, and vague promises of future action" that has been repeated for the past nine years. *In re Pesticide Action Network, 798 F.3d 809, 811* (9th Cir. 2015). EPA's continued delay is all the more significant since there are "considerable human health interests prejudiced by it." *Id.* at 814.
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> EPA's nine-year delay in taking action was "objectively extreme" when we received PANNA's petition for mandamus, and nothing has changed that would justify EPA's continued failure to respond to the pressing health concern presented by chlorpyrifos [citing *Public Citizen Health Research Grp. v. Chao*, 314 F.3d 143, 154-55 (3d Cir. 2002)].

(Dkt. Entry 51, p. 4).

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[7] The Ninth Circuit also ordered EPA to take final action on the NRDC/PANNA petition and the Administrator's order deals with only that aspect of the Court's ruling. Nevertheless, it is questionable whether the Administrator's order complies with even that portion of the Court's directive because it purports to initiate a new administrative proceeding involving objections and a potential evidentiary hearing, which is likely to take years to reach finality and avoids judicial review on the merits.

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The Administrator's order violates the Ninth Circuit's orders, which were intended to compel EPA to make a final decision on the merits of the proposed tolerance revocation rule.[8] The Ninth Circuit's orders were not intended to allow the Administrator to effectively grant EPA an indefinite extension of time to issue a final rule. The Administrator's order not only extends the time frame for finally determining whether tolerances are safe, it is designed to avoid judicial review on the merits.[9]

Thus, the March 29, 2017 order is unlawful because it violates a critical component of the Ninth Circuit's orders since EPA has not taken final action on the merits of the proposed tolerance revocation rule.

3. The States Object to EPA Delaying a Ruling on These Objections and to EPA Convening an Evidentiary Hearing.

As set forth above, the States' objections to the March 29, 2017 order are strictly legal in nature and raise no material issues of fact. The objections therefore do not warrant an evidentiary hearing and the States would object to EPA convening such a hearing. Indeed, a hearing cannot be convened under the standard in FFDCA Section 408(g)(2)(B) because a hearing is not "necessary to receive factual evidence relevant to material issues of fact raised by the objections." 21 U.S.C. § 346a(g)(2)(B). Because the States' objections do not raise material issues of fact, a hearing would not be appropriate.

The FFDCA requires EPA to rule on objections "as soon as practicable." 21 U.S.C. § 346a(g)(2)(C). In using this term, the FFDCA imposes a reasonableness standard as to the timing of EPA's ruling on objections, particularly those that are purely legal in nature and limited. In responding to strictly legal objections, we believe the term "as soon as practicable" imposes on EPA an abbreviated time frame for response and final decision. The States assert that EPA reasonably can rule on these objections no more than 60 days from their submission, or by no later than August 5, 2017.

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[8] In making its decision, the Ninth Circuit presumed EPA's compliance with the law and its orders, which by implication compelled EPA's finding that any tolerances remaining after final agency action were safe.

[9] Nevertheless, the Administrator's order is the functional equivalent of a final order issued under FFDCA Section 408(g)(2) because of the extensive public comment and administrative processes that preceded it. See 21 U.S.C. § 346a(g)(2)(c) and (h)(1), (5).

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Conclusion

EPA's March 29, 2017 order denied the NRDC/PANNA petition to revoke chlorpyrifos tolerances, effectively leaving those tolerances in place within the meaning of FFDCA Section 408, 21 U.S.C § 346a(b)(2)(A)(i). In taking this action, EPA failed to apply the required FFDCA standard and find that the tolerances are safe and that there is a reasonable certainty that no harm will result from aggregate human exposure. EPA's order is unlawful and conflicts with two notices of proposed rulemaking stating that the agency could not find the tolerances safe. It also violates the orders of the Ninth Circuit, which required EPA to take final action on the proposed revocation of chlorpyrifos tolerances. For the foregoing reasons, the States' request that EPA vacate the Administrator's March 29, 2017 order and issue a final tolerance revocation rule in compliance with the requirements of the FFDCA and the Ninth Circuit's orders.

Respectfully submitted,

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