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UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

LEAGUE OF UNITED LATIN AMERICAN CITIZENS; PESTICIDE ACTION NETWORK NORTH AMERICA; NATURAL RESOURCES DEFENSE COUNCIL; CALIFORNIA RURAL LEGAL ASSISTANCE FOUNDATION; FARMWORKER ASSOCIATION OF FLORIDA; FARMWORKER JUSTICE GREENLATINOS; LABOR COUNCIL FOR LATIN AMERICAN ADVANCEMENT; LEARNING DISABILITIES ASSOCIATION OF AMERICA; NATIONAL HISPANIC MEDICAL ASSOCIATION; PINEROS Y CAMPESINOS UNIDOS DEL NOROESTE; AND UNITED FARM WORKERS,

Petitioners,

v.

SCOTT PRUITT, ADMINISTRATOR OF UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, AND UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

PETITION FOR REVIEW	

PATTI A. GOLDMAN MARISA C. ORDONIA KRISTEN L. BOYLES Earthjustice 705 Second Avenue, Suite 203 Seattle, WA 98104 Case: 17-71636, 06/05/2017, ID: 10460406, DktEntry: 1-1, Page 2 of 20

(206) 343-7340 | Phone (206) 343-1526 | Fax pgoldman@earthjustice.org mordonia@earthjustice.org kboyles@earthjustice.org Attorneys for Petitioners

League of United Latin American Citizens, Pesticide Action Network North America ("PANNA"), Natural Resources Defense Council ("NRDC"), California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, GreenLatinos, Labor Council for Latin American Advancement, Learning Disabilities Association of America, National Hispanic Medical Association, Pineros y Campesinos Unidos del Noroeste, and United Farm Workers, hereby petition the United States Court of Appeals for the Ninth Circuit for review of the order issued by Respondent Scott Pruitt, Administrator of the United States Environmental Protection Agency ("EPA"), entitled "Chlorpyrifos: Order Denying PANNA and NRDC's Petition to Revoke Tolerances," issued March 29, 2017, and published at 82 Fed. Reg. 16,581 (April 5, 2017) (attached as Exhibit A). Petitioners and their members will be adversely affected by the Pruitt Order, and PANNA, California Rural Legal Assistance Foundation, United Farm Workers, and Pineros y Campesinos Unidos del Noroeste have their principal places of business in this Circuit.

This case is related to *In re Pesticide Action Network North America and Natural Resources Defense Council v. U.S. Environmental Protection Agency*, No. 14-72794, because the two cases raise the same or closely related issues and involve the same events. *See* Ninth Circuit Court of Appeals Rule 28-2.6 - Statement of Related Cases. A motion for further mandamus relief is pending

before the panel that has retained jurisdiction over Case No. 14-72794.

Respectfully submitted this 5th day of June, 2017.

PATTI A. GOLDMAN MARISA C. ORDONIA KRISTEN L. BOYLES

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Attorneys for Petitioners

CORPORATE DISCLOSURE STATEMENT

Petitioners, League of United Latin American Citizens, Pesticide Action
Network North America, Natural Resources Defense Council, California Rural
Legal Assistance Foundation, Farmworker Association of Florida, Farmworker
Justice, GreenLatinos, Labor Council for Latin American Advancement, Learning
Disabilities Association of America, National Hispanic Medical Association,
Pineros y Campesinos Unidos del Noroeste, and United Farm Workers, have no
parent companies, subsidiaries, or affiliates that have issued shares to the public in
the United States or abroad.

Respectfully submitted this 5th day of June, 2017.

PATTI A. GOLDMAN MARISA C. ORDONIA KRISTEN L. BOYLES

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Attorneys for Petitioners

DECLARATION OF SERVICE

I am a citizen of the United States and a resident of the State of Washington.

I am over 18 years of age and not a party to this action. My business address is

705 Second Avenue, Suite 203, Seattle, Washington 98104.

On June 5, 2017, I served a true and correct copy of:

1. Petition for Review and Exhibit A.

on the following parties:

Scott Pruitt	
Administrator	via certified U.S. Mail
U.S. Environmental Protection Agency	via certified
William Jefferson Clinton Bldg. (WJC South)	☐ via e-mail
1200 Pennsylvania Avenue, N.W., Room 3000	via ECF filing system
Washington, D.C. 20004	_
(202) 564-4700 Phone	
Infferson Paguragard Sassions III	
Jefferson Beauregard Sessions III	Via contified U.S. Mail
United States Attorney General	via certified U.S. Mail
U.S. Department of Justice	
950 Pennsylvania Avenue, N.W.	☐ via e-mail
Washington, D.C. 20530-0001	☐ via ECF filing system
(202) 514-2001 Phone	
Brian Stretch	
U.S. Attorney's Office	via certified U.S. Mail
Northern District of California	via first-class U.S. mail
Federal Courthouse	☐ via e-mail
450 Golden Gate Avenue	via ECF filing system
San Francisco, CA 94102	
(415) 436-7200 Phone	

I, Rachel Leigh, declare under penalty of perjury that the foregoing is true and correct. Executed on this 5th day of June, 2017, at Seattle, Washington.

Rachel Leigh, Litigation Assistant

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AT A. A
Exhibit A

authorizes the Secretary of Energy to prescribe test procedures that are reasonably designed to produce results that measure energy efficiency, energy use, or estimated operating costs during a representative average-use cycle, and that are not unduly burdensome to conduct. (42 U.S.C. 6293(b)(3)) The test procedure for battery chargers is contained in Title 10 of the Code of Federal Regulations (CFR) part 430, subpart B, appendix Y, *Uniform Test Method for Measuring the Energy Consumption of Battery Chargers*.

The regulations set forth in 10 CFR 430.27 contain provisions that allow a person to seek a waiver from the test procedure requirements for a particular basic model of a type of covered product when the petitioner's basic model for which the petition for waiver was submitted contains one or more design characteristics that: (1) Prevent testing according to the prescribed test procedure, or (2) cause the prescribed test procedures to evaluate the basic model in a manner so unrepresentative of its true energy consumption characteristics as to provide materially inaccurate comparative data. 10 CFR 430.27(a)(1).DOE may grant the waiver subject to conditions, including adherence to alternate test procedures. 10 CFR 430.27(f)(2).

II. Dyson's Petition for Waiver: Assertions and Determinations

On April 7, 2016, Dyson filed a petition for waiver from the DOE test procedure for battery chargers under 10 CFR 430.27 for the battery charger used in their robotic vacuum cleaner model RB01, marketed as the Dyson 360-Eye (Robot), which is required to be tested using the DOE battery charger test procedure at 10 CFR 430.23(aa) and detailed at 10 CFR part 430, subpart B, appendix Y. In its petition, Dyson asks that the requirement contained in the DOE test procedure for battery chargers provided in 10 CFR part 430, subpart B, appendix Y, section 4.4, Limiting Other Non-Battery-Charger Functions, be waived with regard to testing of the Robot battery charger. According to subsection 4.4.b (and a related provision at section 5.6.c.1), any function controlled by the user and not associated with the battery charging process must be switched off or be set to the lowest power-consuming mode.

Dyson asserts that in order to provide the user with the advanced setting and management features of the Robot, the relevant functionalities and circuitry have to be powered at all times. Accordingly, Dyson does not believe it appropriate to make these functions, which are not associated with the battery charging process, user controllable because they are an integral part of the Robot itself. Therefore, in order to ascertain the true energy consumption characteristics of the battery charger during the test, Dyson seeks permission to switch off these functions by a means that is not controlled by the user.

Dyson also requested an interim waiver from the existing DOE test procedure, which DOE granted. See 81 FR at 62489. After reviewing the alternate procedure suggested by Dyson, DOE granted the interim waiver because DOE determined that Dyson's petition for waiver will likely be granted and decided that it was desirable for public policy reasons to grant Dyson immediate relief pending a determination on the petition for waiver. Dyson's petition was published in the Federal Register on September 9, 2016. 81 FR 62489. DOE received no comments regarding Dyson's petition.

On May 20, 2016, DOE published a test procedure final rule that adopted amendments to the battery charger test procedure found in Appendix Y. 81 FR 31827. Subsequently, on December 12, 2016, DOE issued a separate final rule to add a discrete test method for uninterruptible power supplies to the battery charger test procedure. 81 FR 89806. Neither of these final rules amended the provisions of the battery charger test procedure from which Dyson sought a waiver. Since the amendments in these final rules did not address the issues presented in the waiver petition, Dyson's interim waiver has remained in effect while DOE has evaluated the waiver petition. 10 CFR 430.27(h).

III. Consultations With Other Agencies

DOE consulted with the Federal Trade Commission (FTC) staff concerning the Dyson petition for waiver. The FTC staff did not have any objections to granting a waiver to Dyson.

IV. Order

After careful consideration of all the material that was submitted by Dyson and consultation with the FTC staff, in accordance with 10 CFR 430.27, it is ordered that:

(1) The petition for waiver submitted by the Dyson Inc. (Case No. BC–001) is hereby granted as set forth in the paragraphs below.

(2) Dyson must test and rate the Dyson basic models specified in paragraph (3) on the basis of the current test procedure contained in 10 CFR part 430, subpart B, appendix Y, except that Dyson, notwithstanding the instructions in Appendix Y sections 3.2.4 and 3.3.6,

may disable power to functions not associated with the battery charging process by isolating a terminal of the battery pack using isolating tape, as shown in the Appendices to the petition for waiver.

- (3) This order applies only to the following basic model: RB01, marketed as the Dyson 360-Eye ("Robot"), battery charger.
- (4) This waiver shall remain in effect consistent with the provisions of 10 CFR 430.27.

Issued in Washington, DC, on March 27, 2017.

Steven G. Chalk,

Acting Assistant Secretary, Energy Efficiency and Renewable Energy

[FR Doc. 2017–06732 Filed 4–4–17; 8:45 am]

BILLING CODE -P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2007-1005; FRL-9960-77]

Chlorpyrifos; Order Denying PANNA and NRDC's Petition To Revoke Tolerances

AGENCY: Environmental Protection Agency (EPA). **ACTION:** Order.

SUMMARY: In this Order, EPA denies a petition requesting that EPA revoke all tolerances for the pesticide chlorpyrifos under section 408(d) of the Federal Food, Drug, and Cosmetic Act and cancel all chlorpyrifos registrations under the Federal Insecticide, Fungicide and Rodenticide Act. The petition was filed in September 2007 by the Pesticide Action Network North America (PANNA) and the Natural Resources Defense Council (NRDC).

DATES: This Order is effective April 5, 2017. Objections and requests for hearings must be received on or before June 5, 2017, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I. of the **SUPPLEMENTARY INFORMATION.**)

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2007-1005, is available at http://www.regulations.gov or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal

holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT:

Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–0206; email address: OPPChlorpyrifosInquiries@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

In this document EPA denies a petition by PANNA and the NRDC to revoke pesticide tolerances and cancel pesticide registrations. This action may also be of interest to agricultural producers, food manufacturers, or pesticide manufacturers. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (North American Industrial Classification System (NAICS) code 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), *e.g.*, cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers, greenhouse, nursery, and floriculture workers; residential users.

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The NAICS codes have been provided to assists you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How can I get copies of this document and other related information?

EPA has established a docket for this action under Docket ID No. EPA-HQ-OPP-2007-1005. Additional information relevant to this action is located in the chlorpyrifos registration review docket under Docket ID No,

EPA-HQ-OPP-2008-0850 and the chlorpyrifos tolerance rulemaking docket under Docket ID No, EPA-HQ-OPP-2015-0653. To access the electronic docket, go to http:// www.regulations.gov, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov Web site to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m. Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-

C. Can I file an objection or hearing request?

Under section 408(g) of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a(g)), any person may file an objection to any aspect of this order and may also request a hearing on those objections. You must file your objection or request a hearing on this order in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2007-1005 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before June 5, 2017, and may be submitted by one of the following methods:

- *Mail:* U.S. EPA Office of Administrative Law Judges, Mailcode 1900R, 1200 Pennsylvania Ave. NW., Washington, DC 20460
- Hand Delivery: U.S. Environmental Protection Agency Office of Administrative Law Judges, Ronald Reagan Building, Rm. M1200, 1300 Pennsylvania Ave. NW., Washington, DC 20004. Deliveries are only accepted during the Office's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays). Special arrangements should be made for deliveries of boxed information. The Office's telephone number is (202) 564–6255.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain CBI for inclusion in the public docket that is described in I.B.1 above. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2007-1005, by one of the following methods:

• Federal eRulemaking Portal: http://www.regulations.gov. Follow the on-line instructions for submitting comments.

• Mail: U.S. Environmental Protection Agency Office of Pesticide Programs (OPP) Public Regulatory Docket (7502P), 1200 Pennsylvania, Ave. NW., Washington, DC 20460–0001.

• Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

D. What should be included in objections?

The objection stage is the second stage in the petition process under FFDCA section 408. This multi-stage process is initiated by a petition requesting establishment, modification, or revocation of a tolerance. Once EPA makes a decision on a petition, and publishes its decision in the Federal Register, the second stage of the petition process is triggered. At this point, parties who disagree with EPA's decision, whether it is a decision to grant or deny the petition, may file objections with EPA to the decision made. The objection stage gives parties a chance to seek review of EPA's decision before the Agency. This is an opportunity for parties to contest the conclusions EPA reached and the determinations underlying those conclusions. As an administrative review stage, it is not an opportunity to raise new issues or arguments or present facts or information that were available earlier. On the other hand, parties must do more than repeat the claims in the petition. The objection stage is the opportunity to challenge EPA's decision on the petition. An objection fails on its

face if it does not identify aspects of EPA's decision believed to be in error and explain the reason why EPA's decision is incorrect. This two-stage process insures that issues are fully aired before the Agency and a comprehensive record is compiled, prior to judicial review.

II. Introduction

A. What action is the Agency taking?

In this document, EPA denies a petition by PANNA and the NRDC. In a petition dated September 12, 2007, PANNA and NRDC (the petitioners) requested that EPA revoke all tolerances for the pesticide chlorpyrifos established under section 408 of the FFDCA. (Ref. 1) The petition also sought the cancellation of all chlorpyrifos pesticide product registrations under section 6 the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. 136d. The PANNA and NRDC petition (the Petition) raised the following claims regarding EPA's reregistration and active registrations of chlorpyrifos in support of the request for tolerance revocation and product cancellation:

- 1. EPA has ignored genetic evidence of vulnerable populations.
- 2. EPA has needlessly delayed a decision regarding endocrine disrupting effects.
- 3. EPA has ignored data regarding cancer risks.
- 4. EPA's 2006 cumulative risk assessment (CRA) for the organophosphates misrepresented risks and failed to apply FQPA 10X safety factor. [For convenience's sake, the legal requirements regarding the additional safety margin for infants and children in section 408(b)(2)(C) of the FFDCA are referred to throughout this response as the "FOPA 10X safety factor" or simply the "FQPA safety factor." Due to Congress' focus on both pre- and postnatal toxicity, EPA has interpreted this additional safety factor as pertaining to risks to infants and children that arise due to pre-natal exposure as well as to exposure during childhood years.]
- 5. EPA has over-relied on registrant
- 6. EPA has failed to properly address the exporting hazard in foreign countries from chlorpyrifos.
- 7. EPA has failed to quantitatively incorporate data demonstrating long-lasting effects from early life exposure to chlorpyrifos in children.
- 8. EPA has disregarded data demonstrating that there is no evidence of a safe level of exposure during prebirth and early life stages.
- 9. EPA has failed to cite or quantitatively incorporate studies and

clinical reports suggesting potential adverse effects below 10% cholinesterase inhibition.

10. EPA has failed to incorporate inhalation routes of exposure.

In this order EPA is denying the Petition in full. EPA provided the petitioners with two interim responses on July 16, 2012, and July 15, 2014, respectively. The July 16, 2012, response denied claim 6 (export hazard) completely and that portion of the response was a final agency action. The remainder of the July 16, 2012, response and the July 15, 2014, response expressed EPA's intention to deny six other petition claims (1-5 and 10). [In the 2012 response, EPA did, however, inform petitioners of its approval of label mitigation (in the form of rate reductions and spray drift buffers) to reduce bystander risks, including risks from inhalation exposure, which in effect partially granted petition claim 10.] EPA made clear in both the 2012 and 2014 responses that, absent a request from petitioners, EPA's denial of those six claims would not be made final until EPA finalized its response to the entire Petition. Petitioners made no such request. EPA is finalizing its denial of those six claims in this order.

The remaining claims (7–9) all related to same issue: Whether the potential exists for chlorpyrifos to cause neurodevelopmental effects in children at exposure levels below EPA's existing regulatory standard (10% cholinesterase inhibition). While these claims raised novel, highly complex and unresolved scientific issues, EPA decided it would nonetheless expedite the registration review of chlorpyrifos under FIFRA section 3(g), and attempt to address these issues several years in advance of the October 1, 2022 deadline for completing that review. Accordingly, EPA also decided as a policy matter that it would address the Petition claims raising these matters on a similar timeframe. Although EPA had expedited its registration review to address these issues, the petitioners were not satisfied with EPA's progress in responding to the Petition and they brought legal action in the 9th Circuit Court of Appeals to compel EPA to either issue an order denying the Petition or to grant the Petition by initiating the tolerance revocation process. In August 2015, the 9th Circuit issued a ruling in favor of the petitioners and ordered EPA to respond to the Petition by either denying the Petition or issuing a proposed or final rule revoking chlorpyrifos tolerances. In re Pesticide Action Network of North America v. EPA, 798 F.3d (9th Cir. 2015).

On November 6, 2015, pursuant to the 9th Circuit's order, EPA proposed to revoke all chlorpyrifos tolerances based in part on uncertainty surrounding the potential for chlorpyrifos to cause neurodevelopmental effects—the issue raised in petition claims 7-9. Following publication of the proposal, the 9th Circuit announced that it would retain jurisdiction over this matter and on August 12, 2016, the court further ordered EPA to complete a final petition response by March 31, 2017 and made clear that no further extensions would be granted. On November 17, 2016, EPA published a notice of data availability that released for public comment EPA's revised risk assessment that proposed a new regulatory point of departure based on the potential for chlorpyrifos to result in adverse neurodevelopmental effects.

Following a review of comments on both the November 2015 proposal and the November 2016 notice of data availability, 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 is warranted to achieve greater certainty as to whether the potential exists for adverse neurodevelopmental effects to occur from current human exposures 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. As noted, Congress has provided that EPA must complete registration review by October 1, 2022. Because the 9th Circuit's August 12, 2016 order has made clear, however, that further extensions to the March 31, 2017 deadline for responding to the Petition would not be granted, EPA is today also denying all remaining petition claims.

B. What is the Agency's authority for taking this action?

Under section 408(d)(4) of the FFDCA, EPA is authorized to respond to a section 408(d) petition to revoke tolerance either by issuing a final rule revoking the tolerances, issuing a proposed rule, or issuing an order denying the Petition.

III. Statutory and Regulatory Background

A. FFDCA/FIFRA and Applicable Regulations

1. In general. EPA establishes maximum residue limits, or "tolerances," for pesticide residues in food and feed commodities under section 408 of the FFDCA. Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is "adulterated" under section 402 of the FFDCA and may not be legally moved in interstate commerce. Section 408 was substantially rewritten by the Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170, 110 Stat. 1489 (1996)), which established a detailed safety standard for pesticides and integrated EPA's regulation of pesticide food residues under the FFDCA with EPA's registration and re-evaluation of pesticides under FIFRA. The standard for issuing or maintaining a tolerance under section 408(b)(2)(A)(i) of the FFDCA is whether it is "safe." "Safe" is defined by section 408(b)(2)(A)(ii) to mean 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."

While the FFDCA authorizes the establishment of legal limits for pesticide residues in food, section 3(a) of FIFRA requires the approval of pesticides prior to their sale and distribution, and establishes a registration regime for regulating the use of pesticides. FIFRA regulates pesticide use in conjunction with its registration scheme by requiring EPA review and approval of pesticide labels and specifying that use of a pesticide inconsistent with its label is a violation of federal law. In the FQPA, Congress integrated action under the two statutes by requiring that the safety standard under the FFDCA be used as a criterion in FIFRA registration actions as to pesticide uses which result in dietary risk from residues in or on food, (see FIFRA section 2(bb)), and directing that EPA coordinate, to the extent practicable, revocations of tolerances with pesticide cancellations under FIFRA. (See FFDCA section 408(l)(1).) Under section 3(g) of FIFRA, EPA is required to re-evaluate pesticides under the FIFRA standard—which includes a determination regarding the safety of existing FFDCA tolerances—every 15 years under a program known as "registration review." The deadline for

completing the registration review for chlorpyrifos is October 1, 2022.

2. Procedures for establishing, amending, or revoking tolerances. Tolerances are established, amended, or revoked by rulemaking under the unique procedural framework set forth in the FFDCA. Generally, a tolerance rulemaking is initiated by the party seeking to establish, amend, or revoke a tolerance by means of filing a petition with EPA. (See FFDCA section 408(d)(1).) EPA publishes in the Federal **Register** a notice of the petition filing and requests public comment. After reviewing the petition, and any comments received on it, section 408(d)(4) provides that EPA may issue a final rule establishing, amending, or revoking the tolerance, issue a proposed rule to do the same, or deny the

Once EPA takes final action on the petition by establishing, amending, or revoking the tolerance or denying the petition, section 408(g)(2) allows any party to file objections with EPA and seek an evidentiary hearing on those objections. Objections and hearing requests must be filed within 60 days. Section 408(g)(2)(B) provides that EPA shall "hold a public evidentiary hearing if and to the extent the Administrator determines that such a public hearing is necessary to receive factual evidence relevant to material issues of fact raised by the objections." EPA regulations make clear that hearings will only be granted where it is shown that there is 'a genuine and substantial issue of fact," the requestor has identified evidence 'which "would, if established, resolve one or more of such issues in favor of the requestor," and the issue is "determinative" with regard to the relief requested. (40 CFR 178.32(b).) Further, a party may not raise issues in objections unless they were part of the petition and an objecting party must state objections to the EPA decision and not just repeat the allegations in its petition. Corn Growers v. EPA, 613 F.2d 266 (D.C. Cir. 2010), cert. denied, 131 S. Ct. 2931 (2011). EPA's final order on the objections is subject to judicial review. (21 U.S.C. 346a(h)(1).)

IV. Chlorpyrifos Regulatory Background

Chlorpyrifos (0,0-diethyl-0-3,5,6-trichloro-2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated organophosphate (OP) insecticide that has been registered for use in the United States since 1965. By pounds of active ingredient, it is the most widely used conventional insecticide in the country. Currently registered use sites include a large variety of food crops (including

tree fruits and nuts, many types of small fruits and vegetables, including vegetable seed treatments, grain/oilseed crops, and cotton, for example), and non-food use settings (e.g., ornamental and agricultural seed production, nonresidential turf, industrial sites/rights of way, greenhouse and nursery production, sod farms, pulpwood production, public health and wood protection). For some of these crops, chlorpyrifos is currently the only costeffective choice for control of certain insect pests. In 2000, the chlorpyrifos registrants reached an agreement with EPA to voluntarily cancel all residential use products except those registered for ant and roach baits in child-resistant packaging and fire ant mound treatments.

In 2006, EPA completed FIFRA section 4 reregistration and FFDCA tolerance reassessment for chlorpyrifos and the OP class of pesticides. Having completed reregistration and tolerance reassessment, EPA is required to complete the next re-evaluation of chlorpyrifos under the FIFRA section 3(g) registration review program by October 1, 2022. Given ongoing scientific developments in the study of the OPs generally, in March 2009 EPA announced its decision to prioritize the FIFRA section 3(g) registration review of chlorpyrifos by opening a public docket and releasing a preliminary work plan to complete the chlorpyrifos registration review by 2015-7 years in advance of the date required by law.

The registration review of chlorpyrifos and the OPs has presented EPA with numerous novel scientific issues that the agency has taken to multiple FIFRA Scientific Advisory Panel (SAP) meetings since the completion of reregistration. [The SAP is a federal advisory committee created by section 25(d) of FIFRA, that serves as EPA's primary source of peer review for significant regulatory and policy matters involving pesticides.] Many of these complex scientific issues formed the basis of the 2007 petition filed by PANNA and NRDC and EPA therefore decided to address the Petition on a similar timeframe to EPA's expedited registration review schedule.

Although EPA expedited the chlorpyrifos registration review in an attempt to address the novel scientific issues raised by the Petition in advance of the statutory deadline, the petitioners were dissatisfied with the pace of EPA's response efforts and have sued EPA in federal court on three separate occasions to compel a faster response to the Petition. As explained in Unit V., EPA had addressed 7 of the 10 claims asserted in the Petition by either

denying the claim, issuing a preliminary denial or approving label mitigation to address the claims, but on June 10, 2015, in the PANNA decision, the U.S. Court of Appeals for the Ninth Circuit signaled its intent to order EPA to complete its response to the Petition and directed EPA to inform the court how-and by when-EPA intended to respond. On June 30, 2015, EPA informed the court that it intended to propose by April 15, 2016, the revocation of all chlorpyrifos tolerances in the absence of pesticide label mitigation that ensures that exposures will be safe. On August 10, 2015, the court rejected EPA's time line and issued a mandamus order directing EPA to "issue either a proposed or final revocation rule or a full and final response to the administrative Petition by October 31, 2015.'

On October 30, 2015, EPA issued a proposed rule to revoke all chlorpyrifos tolerances which it published in the Federal Register on November 6, 2015 (80 FR 69080). On December 10, 2015, the Ninth Circuit issued a further order requiring EPA to complete any final rule (or petition denial) and fully respond to the Petition by December 30, 2016. On June 30, 2016, EPA sought a 6-month extension to that deadline in order to allow EPA to fully consider the most recent views of the FIFRA SAP with respect to chlorpyrifos toxicology. The FIFRA SAP report was finalized and made available for EPA consideration on July 20, 2016. (Ref. 2) On August 12, 2016, the court rejected EPA's request for a 6-month extension and ordered EPA to complete its final action by March 31, 2017 (effectively granting EPA a three-month extension). On November 17, 2016, EPA published a notice of data availability (NODA) seeking public comment on both EPA's revised risk and water assessments and reopening the comment period on the proposal to revoke all chlorpyrifos (81 FR 81049). The comment period for the NODA closed on January 17, 2017.

V. Ruling on Petition

This order denies the Petition on the nine remaining grounds for which EPA has not issued a final denial that can be the subject of objections under section 408(g)(2) of the FFDCA. As noted in Unit II, on July 16, 2012, EPA denied as final agency action petitioners' claim 6 that the registration of chlorpyrifos created an export hazard for workers in foreign countries. That response and the response of July 15, 2014, also included EPA's preliminary denial of petition claims 1–5 and 10 (except to the extent EPA granted that claim) and EPA's responses to those claims are now

incorporated into this order as set forth below. This unit also includes EPA's basis for denying petition claims 7–9. Each specific petition claim is summarized in this Unit V. immediately prior to EPA's response to the claim.

1. Genetic Evidence of Vulnerable Populations

a. Petitioners' claim. Petitioners claim that as part of EPA's reregistration decision (which was completed in 2006 with the completion of the organophosphate cumulative risk assessment) the Agency failed to calculate an appropriate intra-species uncertainty factor (i.e., within human variability) for chlorpyrifos in both its aggregate and cumulative risk assessments (CRA). They assert that certain relevant, robust data, specifically the Furlong et al. (2006) study (Ref. 3) that addresses intra-species variability in the behavior of the detoxifying enzyme paraoxonase (PON1), indicate that the Agency should have applied an intra-species safety factor "of at least 150X in the aggregate and cumulative assessments" rather than the 10X factor EPA applied. Petitioners conclude by noting that applying an intra-species factor of 100X or higher would require setting tolerances below the level of detection, which therefore should compel EPA to revoke all chlorpyrifos tolerances.

b. Agency Response. Petitioners are correct that the Agency, as part of the 2006 OP CRA, evaluated, but did not rely on Furlong et al. in setting the intraspecies uncertainty factor for that assessment. The Agency did not rely on the results of the PON1 data in the OP CRA because these data do not take into consideration the complexity of OP metabolism, which involves multiple metabolic enzymes, not just PON1. In addition, EPA believes the methodology utilized in the Furlong et al. study to measure intra-species variability—i.e., combining values from multiple species (transgenic mice and human) to determine the range of sensitivity within a single species—is not consistent with well-established international risk assessment practices. Further, EPA believes that petitioners' assertion that the Furlong et al. study supports an intra-species uncertainty factor of at least 150X is based on an analysis of the data that is inconsistent with EPA policy and widely-accepted international guidance on the development of intra-species uncertainty factors. In addition, the 2008 FIFRA SAP did not support the use of the Furlong et al (2006) study alone in deriving an intra-species factor. For these reasons, and as further

explained below, EPA believes it is not appropriate to solely rely on the results of the Furlong et al. study, or petitioners' interpretation of those results, for purposes of determining the intra-species uncertainty factor. To determine that factor, EPA first uses science tools to quantitatively characterize human variability in both exposure and dosimetry, and then determines the appropriate intra-species uncertainty factor to protect sensitive populations. Specifically, for chlorpyrifos, EPA uses a physiologically-based pharmacokinetic (PBPK) model to account for human variability in the absorption, distribution, metabolism and excretion (ADME) of chemicals based on key physiological, biochemicals, and physicochemical determinants of these ADME processes, including the influence of PON1 variability.

Addressing human variability and sensitive populations is an important aspect of the Agency's risk assessment process. The Agency is well aware of the issue of PON1 and has examined the scientific evidence on this source of genetic variability. PON1 is one of the key detoxification enzymes of chlorpyrifos and is included as part of the PBPK model used by EPA in the 2014 human health risk assessment (HHRA) and 2016 revised risk assessment. Specifically, PON1 is an Aesterase which can metabolize chlorpyrifos-oxon without inactivating the enzyme. (Ref. 4) Indeed, as part of the 2008 SAP, EPA performed a literature review of PON1 and its possible use in informing the intraspecies (i.e., within human variability) uncertainty factor. This literature review can be found in the draft Appendix E: Data Derived Extrapolation Factor Analysis to the draft Science Issue Paper: Chlorpyrifos Hazard and Dose Response Characterization. (Ref. 5) In sum, the Agency considered available PON1 data from more than 25 studies from diverse human populations worldwide.

The Agency focused on the PON1-192 polymorphism since it has been linked to chlorpyrifos-oxon sensitivity in experimental toxicology studies and, has been evaluated in epidemiology studies attempting to associate PON1 status with health outcomes following OP pesticide exposure in adults and children (Holland et al., 2006; Chen et al., 2003. (Ref. 6). [Note, Holland et al. (2006) and Furlong et al. (2006) report findings from the same cohort. The Holland reference provides enzymes activities for specific polymorphisms in Table 4; the Furlong paper does not report such values and provides

information primarily in graphical form.] However, EPA believes that focusing on PON1 variability in isolation from other metabolic action is not an appropriate approach for developing a data-driven uncertainty factor. The Agency solicited feedback from the SAP on the utility of the PON1 data, by itself, for use in risk assessment; the SAP was similarly not supportive of using such data in isolation. Specifically, the SAP report

. . the information on PON1 polymorphisms should not be used as the sole factor in a data-derived uncertainty factor for two main reasons: (1) it is only one enzyme in a complex pathway, and is subsequent to the bioactivation reaction; therefore it can only function on the amount of bioactivation product (i.e., chlorpyrifosoxon) that is delivered to it by CYP450); and (2) the genotype of PON1 alone is insufficient to predict vulnerability because the overall level of enzyme activity is ultimately what determines detoxification potential from that pathway; thus, it is better to use PON1 status because it provides information regarding PON1 genotype and activity. Some of the data from laboratory animal studies in PON knockout animals are using an unrealistic animal model and frequently very high dose levels, and do not reflect what might happen in humans. (Ref. 7)

Based on a detailed review of the literature and the comments from the SAP, the Agency has determined that such data are not appropriate for use alone in deriving an intra-species uncertainty factor for use in human health risk assessment. As indicated by the SAP report, multiple factors (e.g., other enzymes such as P450s, carboxylesterases,

butyrylcholinesterase) are likely to impact potential population sensitivity, rendering the results of the PON1 data, by themselves, insufficiently reliable to support a regulatory conclusion about the potential variation of human sensitivity to chlorpyrifos.

Since the 2008 SAP, several epidemiological studies have been published that considered the association between PON status/ genotype and health outcome. Hofmann et al. (2009) recently reported associations between PON1 status and inhibition of butyrylcholinesterase (BuChE) in a group of pesticide handlers in Washington. The authors note that this study requires replication with larger sample size(s) and more blood samples. (Ref. 8) Given the limitations of Hofmann et al., the Agency has not drawn any conclusions from this study. The Q/R-192 and/or C/T-108 polymorphism at the promoter site have been evaluated recently as a factor affecting birth or neurobehavioral

outcomes following gestational exposure to OPs. (Refs. 9, 10, 11) These studies (Eskanazi., et al., 2010 (Ref. 9); Harley et al., 2011 (Ref. 10); Engel et al., 2011 (Ref. 11)) were evaluated by EPA in preparation for the April 2012 SAP review.

Petitioners further emphasize that the Furlong et al. study supports an intraspecies uncertainty factor of over 164X given the range of variability seen in that study. The 164X value is derived from sensitivity observed in transgenic mice expressing human PON1Q-192 compared with mice expressing human PON1R-192 combined with the range of plasma arvlesterase (AREase) from the newborn with the lowest PON1 level compared with the mother with the highest PON1 level from a group of 130 maternal-newborn pairs from the CHAMACOS (Center for the Health Assessment of Mothers and Children of Salinas) cohort.

EPA believes it is fundamentally at odds with international risk assessment practices to combine values from both mouse and human data to determine the potential range of variability within a single species—regardless of whether the test animals express a human PON1 enzyme. As the 2008 FIFRA SAP explained, PON1 is but a single enzyme that should not be considered in isolation to predict the overall level of enzyme activity that may affect human sensitivity to a substance. Using a 164X intra-species uncertainty factor derived from the Furlong et al. study would take this practice one step further by relying upon combined PON1 values from different species with differing overall metabolic activity to derive the intraspecies factor. EPA does not believe this approach is an appropriate means of determining the potential range of intraspecies variability.

Finally, petitioners' assertion that the Furlong study supports an intra-species uncertainty factor of at least 150X is based on an analysis of that study that is inconsistent with EPA policy and widely-accepted international guidance on the development of intra-species uncertainty factors. In deriving the intra-species uncertainty factor in its risk assessments, EPA is guided by the principles of the 2005 IPCS (Ref. 12) guidance on chemical specific adjustment factors (CSAFs) and the EPA's 2014 Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation. (Ref. 13) These guidances recommend that intra-species factors should be extrapolated from a measure of central tendency in the population to a measure in the sensitive population

(i.e., to extrapolate from a typical human to a sensitive human). To base the factor on the difference between the single lowest and highest measurements in a given study, as petitioners suggest in this instance, would likely greatly exaggerate potential intra-species variability. That approach effectively assumes that the point of departure in an EPA risk assessment will be derived from the least sensitive test subject, thereby necessitating the application of an intra-species factor that accounts for the full range of sensitivity across a species. Since EPA does not develop its PoDs in this fashion; the approach suggested by petitioners is not appropriate.

In summary, the Agency has carefully considered the issue of PON1 variability and determined that data addressing PON1 in isolation are not appropriate for use alone in deriving an intraspecies uncertainty factor and that the issue is more appropriately handled using a PBPK model. Further, the derivation of the 164X value advocated by the petitioners is based on combining values from humanized mice with human measured values with a range from highest to lowest; the Furlong et al. derivation is inappropriate and inconsistent with international risk assessment practice. (Ref. 2) The 2008 FIFRA SAP did not support the PON1 data used in isolation. Finally, petitioners' statement that the Furlong et al. study supports an intra-species uncertainty factor of at least 150X likely overstates potential variability. EPA therefore denies this aspect of the Petition.

2. Endocrine Disrupting Effects

a. Petitioners' claim. Petitioners summarize a number of studies evaluating the effects of chlorpyrifos on the endocrine system, asserting that, taken together, the studies "suggest that chlorpyrifos may be an endocrine disrupting chemical, capable of interfering with multiple hormones controlling reproduction and neurodevelopment." The petitioners then assert that EPA should not have delayed consideration of endocrine effects absent finalization of the **Endocrine Disruptor Screening Program** (EDSP) (Ref. 14) and should have quantitatively incorporated the studies into the chlorpyrifos IRED.

b. Agency Response. This portion of the Petition appears largely to be a complaint about the completeness of EPA's reregistration decision and a request that EPA undertake quantitative incorporation of endocrine endpoints into its assessment of chlorpyrifos. The Petition does not explain whether and

how endocrine effects should form the basis of a decision to revoke tolerances. The basis for seeking revocation of a tolerance is a showing that the pesticide is not "safe." Petitioners have neither asserted that EPA should revoke tolerances because effects on the endocrine system render the tolerances unsafe, nor have petitioners submitted a factual analysis demonstrating that aggregate exposure to chlorpyrifos presents an unsafe risk to humans based on effects on the endocrine system. Rather, the Petition appears to collect a number of studies suggesting that chlorpyrifos may have effects on the endocrine system and that EPA should have considered those health impacts at reregistration in a quantitative assessment.

To the extent that petitioners are seeking tolerance revocation on these grounds, the Petition fails to provide a sufficient basis for revocation because, in addition to the preceding defects, the cited data do not provide quantitative data (i.e., endpoints/points of departure) that indicate endocrine effects at doses that are more sensitive than the points of departure used in the chlorpyrifos risk assessment that are based on cholinesterase inhibition. While the cited studies provide qualitative information that exposure to chlorpyrifos may be associated with effects on the androgen and thyroid hormonal pathways, these data alone do not demonstrate that current human exposures from existing tolerances are unsafe. The Agency noted similar effects during its evaluation of information submitted by People for the Ethical Treatment of Animals (PETA) and the Physicians Committee for Responsible Medicine (PCRM) during its review of existing information as part of EPA's EDSP, as discussed below. Based on the review of that data, EPA concluded that the effects seen in those studies do not call into question EPA's prior safety determinations supporting the existing tolerances; the data do not indicate a risk warranting regulatory action, and the petitioners have provided no specific information to alter this determination.

Consequently, the Petition does not support a conclusion that existing tolerances are unsafe due to potential endocrine effects. This portion of the Petition is therefore denied.

As petitioners may be aware, since the filing of the petition, EPA has completed the evaluation of chlorpyrifos under EPA's EDSP, as required under FFDCA section 408(p) that confirms EPA's conclusions. On April 15, 2009, a **Federal Register** notice was published in which chlorpyrifos

was included in the initial list of chemicals (List 1) to receive EDSP Tier 1 test orders. The EDSP program is a two-tiered screening and testing program, Tier 1 and Tier 2 tests. Tier 1 includes 11 assays in the battery; these data are intended to allow EPA to determine whether certain substances (including pesticide active and other ingredients) have the potential to interact with the endocrine system and cause an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The purpose of Tier 2 tests is to identify and establish a quantitative, dose-response relationship for any adverse effects that might result from the interactions with the endocrine system.

On November 5, 2009, EPA issued Tier 1 test orders to the registrants of chlorpyrifos, requiring a battery of 11 screening assays to identify the potential to interact with the estrogen, androgen, or thyroid hormonal systems. (Ref. 15)

The agency received and reviewed all 11 EDSP Tier 1 screening assays for chlorpyrifos. On June 29, 2015, the agency completed the EDSP weight of evidence (WoE) conclusions for the Tier 1 screening assays for List 1 chemicals, including chlorpyrifos. In addition to the Tier 1 data, the WoE evaluations considered other scientifically relevant information (OSRI), including general toxicity data and open literature studies of sufficient quality. In determining whether chlorpyrifos interacts with the estrogen, androgen or thyroid pathways, the agency considered the number and type of effects induced, the magnitude and pattern of responses observed across studies, taxa, and sexes. Additionally, the agency also considered the conditions under which effects occurred, in particular whether or not endocrine-related responses occurred at dose(s) that also resulted in general systemic or overt toxicity. The agency concluded that, based on weight of evidence considerations, EDSP Tier 2 testing is not recommended for chlorpyrifos since there was no evidence of potential interaction with the estrogen, androgen and thyroid pathways. The EDSP Tier 1 WoE assessment and associated data evaluation records for chlorpyrifos are available online. (Ref. 16) This assessment further supports EPA's denial of this portion of the Petition.

3. Cancer Risks

a. Petitioners' claim. Petitioners claim that the Agency "ignored" a December
 2004 National Institutes of Health

Agricultural Health Study (AHS) by Lee et al. (2004) (Ref. 17) that evaluated the association between chlorpyrifos and lung cancer incidence. (Ref. 17) The petition summarizes the results of the AHS study, stating that the incidence of lung cancer has a statistically significant association with chlorpyrifos exposure. The Petition then asserts that these data are highly relevant and therefore should have been referenced in the final aggregate assessment for chlorpyrifos or the OP CRA. Petitioners do not otherwise explain whether and how these data support the revocation of tolerances or the cancellation of pesticide registrations.

b. Agency Response. As explained in the previous section, the basis for seeking revocation of a tolerance is a showing that the pesticide is not "safe." Claiming that EPA failed to reference certain data in its risk assessment regarding carcinogenicity does not amount to illustrating that the tolerances are unsafe. To show a lack of safety, petitioners would have to present some fact-based argument demonstrating that aggregate exposure to chlorpyrifos poses an unsafe carcinogenic risk. Petitioners have not presented such an analysis. Accordingly, EPA is denying the Petition to revoke chlorpyrifos tolerances or cancel chlorpyrifos registrations to the extent the Petition relies on claims pertaining to carcinogenicity.

Despite the inadequacy of petitioners' cancer claims, in the course of the Agency's review of chlorpyrifos, EPA has examined the Lee et al. study cited by petitioners (Ref. 17) among other lines of evidence. EPA has concluded that the Lee et al. investigation does not alter the Agency's weight of evidence determination concerning chlorpyrifos' carcinogenic potential, and therefore does not alter the Agency's current cancer classification for chlorpyrifos. Specifically, the Agency does not believe this evidence raises sufficient grounds for concern regarding chlorpyrifos that EPA should consider

initiating action based upon this information that might lead to revocation of the chlorpyrifos tolerances or cancellation of the chlorpyrifos registrations.

The Agency was aware of the

December 2004 study cited by petitioners. While Lee et al. observed a possible association between chlorpyrifos use and the incidence of lung cancer, the authors also stressed that further evaluation was necessary before concluding the association was causal in nature. (Ref. 17) Additional evaluation is necessary because of

possible alternative explanations for the Lee et al. study, which include unmeasured confounding factors or confounding factors not fully accounted for in the analysis, and possible false positive results due to the performance of multiple statistical tests.

EPA has been a collaborating agency with the AHS since 1993, and continues to closely monitor the AHS literature. The Agency is working closely with the AHS researchers to clearly understand the results of their research efforts to ensure the Agency appropriately interprets these data as future studies are published. Between 2003 and 2009 there have been six nested case-control analyses within the AHS which evaluated the use of a number of agricultural pesticides, including chlorpyrifos, in association with specific anatomical cancer sites, in addition to the previously published cohort study (Ref. 17) cited by the petitioners. As noted below, both the Agency and Health Canada have comprehensively reviewed these data.

In accordance with the Agency's 2005 Guideline for Cancer Risk Assessment (Ref. 18), chlorpyrifos is classified as "Not Likely to be Carcinogenic to Humans" based on the lack of evidence of carcinogenicity in male or female mice and male or female rats. In chronic toxicity/carcinogenicity studies, animals received chlorpyrifos in their feed every day of their lives (78 weeks for mice and 104 weeks for rats) at doses thousands of times greater than any anticipated exposure to humans from authorized uses. There was no evidence of cancer in the experimental animal studies. Additionally, available evidence from in vivo and in vitro assays did not support a mutagenic or genotoxic potential of chlorovrifos.

Recently, the Agency conducted its own review of the six nested casecontrol analyses and one cohort study within the AHS concerning the carcinogenic potential of chlorpyrifos. (Ref. 19) EPA concluded with respect to the AHS lung cancer results that the findings are useful for generating hypotheses, but require confirmation in future studies. This conclusion is consistent with that of researchers from Health Canada. Specifically, Weichenthal et al. (2010) (Ref. 20) published a review article in Environmental Health Perspectives on pesticide exposure and cancer incidence in the AHS cohort. Their review of these same studies concluded that the weight of experimental toxicological evidence does not suggest that chlorpyrifos is carcinogenic, and that epidemiologic results currently available from the AHS are inconsistent, lack replication, and

lack a coherent biologically plausible carcinogenic mode of action. The authors did note positive exposure-response associations for chlorpyrifos and lung cancer in two separate evaluations.

In summary, while there is initial suggestive epidemiological evidence of an association between chlorpyrifos and lung cancer to only form a hypothesis as to a carcinogenic mode of action, additional research (including follow-up AHS research) is needed to test the hypothesis. Consequently, at this time it is reasonable to conclude chlorpyrifos is not a carcinogen in view of the lack of carcinogenicity in the rodent bioassays and the lack of a genotoxic or mutagenic potential. The Agency concludes that existing epidemiological data (including Lee et al.) do not change the current weight of the evidence conclusions. The Agency continues to believe there is not a sufficient basis to alter its assessment of chlorpyrifos as not likely to be carcinogenic to humans when multiple lines of evidence are considered (e.g., epidemiology findings, rodent bioassay, genotoxicity); therefore, chlorpyrifos cancer risk would not be a factor in any potential Agency risk determination to revoke tolerances for chlorpyrifos.

4. CRA Misrepresents Risks, Failed To Apply FQPA10X Safety Factor

a. Petitioners' claim. Petitioners assert that EPA relied on limited data and inaccurate interpretations of data to support its decision to remove the FQPA safety factor in the 2006 OP CRA. Specifically, the petitioners challenge the Agency's use of data from a paper by Zheng et al. (2000) (Ref. 21) claiming that, in contrast to the Agency's analysis of the study data, the data does show an obvious difference between juvenile and adult responses to chlorpyrifos. Petitioners conclude by asserting that the Zheng et al. study supports using a 10X safety factor for chlorpyrifos in the CRA.

b. Agency Response. Petitioners' assertions do not provide a sufficient basis for revoking chlorpyrifos tolerances. As explained previously, the ground for seeking revocation of a tolerance is a showing that the pesticide is not "safe." The petitioners' claim that the data EPA relied upon support a different FQPA safety factor for chlorpyrifos in the CRA does not amount to a showing that chlorpyrifos tolerances are unsafe. To show a lack of safety, petitioners would have to present a factual analysis demonstrating that the lack of a 10X safety factor in the CRA for chlorpyrifos poses unsafe cumulative exposures to the OPs. Petitioners have not made such a

showing. For this reason, EPA is denying the petitioners' request to revoke chlorpyrifos tolerances or cancel chlorpyrifos registrations to the extent that request relies on claims pertaining to EPA's failure to provide a 10X safety factor in the 2006 CRA based on the results of the Zheng et al. study.

Despite the inadequacy of petitioners' FQPA safety factor claims, EPA examined the evidence cited by petitioners for the purpose of evaluating whether the evidence raises sufficient grounds for concern regarding chlorpyrifos that EPA should consider initiating the actions sought by the petitioners.

In general, when the Agency conducts a cumulative assessment, the scope of cumulative risk is limited to the common mechanism endpoint—which in this case of the 2006 OP CRA, was cholinesterase inhibition, the primary toxicity mode of action for the OPs. As such, for the OP CRA, experimental toxicology data on AChE inhibition were used for developing relative potency estimates, points of departure, and informing the FQPA safety factor used in the OP CRA. EPA relied on brain AChE data from adult female rats dosed for 21 days or longer for estimating relative potency and points of departure. At approximately three weeks of oral exposure to OPs, AChE inhibition reaches steady state in the adult rat such that continued dosing does not result in increased inhibition. This timeframe of toxicity (21-days and longer) was selected as there was high confidence in the potency estimates derived from the steady state toxicology studies due to the stability of the AChE inhibition.

The Agency's 2006 OP CRA contained EPA's complete FQPA safety factor analysis, (Ref. 22) which involved consideration of pre-natal and post-natal experimental toxicology studies, in addition to exposure information. In the OP CRA, pre-natal exposure AChE studies in rats show that the fetus is no more sensitive than the dam to AChE inhibition and the fetus is often less sensitive than the dam. Thus, evaluating the potential for increased toxicity of juveniles from post-natal exposure was a key component in determining the magnitude of the FQPA safety factors in the OP CRA. Furthermore, because characteristics of children are directly accounted for in the cumulative exposure assessment, the Agency's methods did not underestimate exposure to OPs.

In the 2006 OP CRA, each OP was assigned a 10X FQPA safety factor unless chemical-specific AChE data on young animals were available to generate a data derived safety factor. To best match the relative potency factor (RPF)s and PODs based on repeated dosing, the Agency used repeated dosing data in juveniles for developing the FQPA safety factors. For chlorpyrifos, at the time of the 2006 OP CRA, the only such data available were from the Zheng et al. literature study.

The petitioners are correct that Dr. Carey Pope of Oklahoma State University provided the Agency with the raw data from the Zheng et al. study. These raw data were used to develop the plot in the 2006 OP CRA which was reproduced in the Petition. Petitioners accurately note that for other OPs a benchmark dose modeling approach was used and that no BMD values were reported for chlorpyrifos. In determining the FQPA safety factor, petitioners claim that the Agency misinterpreted the brain AChE data from Zheng et al.

As shown in the plot reproduced on page 15 of the Petition, the doseresponse data in the Zheng et al. study are variable and lack a monotonic shape at the low dose end of the dose response curve. The Agency acknowledges that at the high dose, the pups appear to be more sensitive. However, at the low dose end of the response curve, relevant for human exposures and, thus, the cumulative risk assessment (i.e., at or near the 10% inhibition level), little to no difference is observed. Therefore, despite the lack of BMD estimates for the Zheng et al. study, the Agency is confident in the value used to address the common mechanism endpoint (AChE inhibition) addressed in the 2006 CRA. Since that time, the Agency attempted BMD modeling of the Zheng et al. data as part of the 2011 preliminary chlorpyrifos HHRA (Ref. 23) which yielded low confidence results due to the variability in the data.

Dow AgroSciences submitted a comparative cholinesterase study (CCA) for chlorpyrifos. CCA studies are specially designed studies to compare the dose-response relationship in juvenile and adult rats. This CCA study includes two components: (1) Acute, single dosing in post-natal day 11 and young adult rats and (2) 11-days of repeating dosing in rat pups from PND11-21 and 11-days of repeated dosing in adult rats. The CCA study for chlorpyrifos is considered by EPA to be high quality and well-designed. The preliminary risk assessment for chlorpyrifos' reports BMD estimates from this CCA study. Specifically, for the repeated dosing portion of the study, the BMD_{10s} of 0.80 (0.69 $BMDL_{10}$) and 1.0 (0.95 BMDL₁₀) mg/kg/day respectively for female pups and adults

support the FQPA safety factor of 1X for the AChE inhibition endpoint used in the 2006 OP CRA. As such, petitioners' claims regarding the CRA and FQPA safety factor is denied.

5. Over-Reliance on Registrant Data

a. Petitioners' claims. Petitioners assert that in reregistering chlorpyrifos EPA "cherry picked" data, "ignoring robust, peer-reviewed data in favor of weak, industry-sponsored data to determine that chlorpyrifos could be reregistered and food tolerances be retained." As such, the Agency's reassessment decision is not scientifically defensible.

b. Agency response. This portion of the Petition does not purport to be an independent basis for revoking chlorpyrifos tolerances or cancelling chlorpyrifos registrations. Rather, this claim appears to underlie petitioners' arguments in other sections of the Petition. While petitioners claim that EPA ignored robust, peer-reviewed data in favor of weak, industry-sponsored data for the reregistration of chlorpyrifos, petitioners do not cite to any studies other than those used to support their other claims. In general, petitioners did not provide any studies in the Petition that EPA failed to evaluate. Since the specific studies cited by petitioners are not associated with this claim, but rather their other claims, EPA's response to the specific studies are, therefore, addressed in its responses to petitioners' other claims. However, EPA explains below why, as a general matter, the Agency does not believe it "over-relied" on registrant data in evaluating the risks of chlorpyrifos in its 2006 reregistration decision.

In spite of petitioners' claim, the Agency does not ignore robust, peerreviewed data in favor of industrysponsored data. Further, EPA has a very public and well-documented set of procedures that it applies to the use and significance accorded all data utilized to inform risk management decisions. Registrant generated data, in response to FIFRA and FFDCA requirements, are conducted and evaluated in accordance with a series of internationally harmonized and scientifically peerreviewed study protocols designed to maintain a high standard of scientific quality and reproducibility. (Refs. 23 and 24.)

Additionally, to further inform the Agency's risk assessment, EPA is committed to the consideration of other sources of information such as data identified in the open, peer-reviewed literature and information submitted by the public as part of the regulatory evaluation of a pesticide. An important

issue, when evaluating any study, is its scientific soundness and quality, and thus, the level of confidence in the study findings to contribute to the risk assessment.

The literature was searched, fully considered, and provided additional information on, chlorpyrifos mode of action, pharmacokinetics, epidemiology, neurobehavioral effects in laboratory animals, and age dependent sensitivity to cholinesterase inhibition.

Therefore, by evaluating registrant data in accordance with internationally harmonized and scientifically peerreviewed study protocols, undertaking thorough open literature searches, and considering information provided by the public, the Agency is confident that its assessment for chlorpyrifos in 2006 was reasonably based upon the best available science at the time of the assessment. Previous sections of this response to petitioners' claims regarding the Agency's inadequate use of various data only further highlights and supports the scientifically defensible results of the Agency's assessment. Petitioners' claim that the Agency overly relies on registrant data is therefore denied.

6. EPA Has Failed To Properly Address the Exporting Hazard in Foreign Countries From Chlorpyrifos

As noted in Unit II., in EPA's July 16, 2012 interim petition response EPA issued a final denial of this claim. That denial constituted final agency action and EPA is not reopening consideration of that claim.

- 7.—9. EPA Failed To Quantitatively
 Incorporate Data Demonstrating LongLasting Effects From Early Life Exposure
 to Chlorpyrifos in Children; EPA
 Disregarded Data Demonstrating That
 There Is No Evidence of a Safe Level of
 Exposure During Pre-Birth and Early
 Life Stages; EPA Failed To Cite or
 Quantitatively Incorporate Studies and
 Clinical Reports Suggesting Potential
 Adverse Effects Below 10%
 Cholinesterase Inhibition
- a. *Petitioners' claims*. The petitioners assert that human epidemiology and rodent developmental neurotoxicity data suggest that pre-natal and early life exposure to chlorpyrifos can result in long-lasting, possibly permanent damage to the nervous system and that these effects are likely occurring at exposure levels below 10% cholinesterase inhibition, EPA's existing regulatory standard for chlorpyrifos and other OPs. They assert that EPA has therefore used the wrong endpoint as a basis for regulation and that, taking into account the full spectrum of toxicity,

chlorpyrifos does not meet the FFDCA safety standard or the FIFRA standard for registration

for registration. b. Agency response. EPA has grouped claims 7-9 together because they fundamentally all raise the same issue: Whether the potential exists for chlorpyrifos to cause neurodevelopmental effects in infants and children from exposures (either to mothers during pregnancy or directly to infants and children) that are lower than those resulting in 10% cholinesterase inhibition—the basis for EPA's longstanding point of departure in regulating chlorpyrifos and other OPs. While petitioners may perhaps disagree, unlike the claims addressed above, these claims were not truly challenges to EPA's 2006 reregistration decision for chlorpyrifos, but rather, challenges to EPA's ongoing approval of chlorpyrifos under FIFRA and the FFDCA that rely in large measure on data published after EPA completed both its 2001 chlorpyrifos Interim Reregistration Decision and the 2006 OP CRA that concluded the reregistration process for chlorpyrifos and all other OPs. As matters that largely came to light after the completion of reregistration, these petition issues are issues to be addressed as part of the registration review of chlorpyrifos—the next round of re-evaluation under section 3(g) of FIFRA. As petitioners are aware, past EPA administrations prioritized the registration review of the OPs in no small measure to begin to focus on the question of OP neurodevelopmental toxicity, which was, and remains, an issue at the cutting edge of science, involving significant uncertainties. EPA has three times presented approaches and proposals to the FIFRA SAP for evaluating recent epidemiologic data (some of which is cited in the Petition) exploring the possible connection between in utero and early childhood exposure to chlorpyrifos and adverse neurodevelopmental effects. The SAP's reports have rendered numerous recommendations for additional study and sometimes conflicting advice for how EPA should consider (or not consider) the epidemiology data in conducting EPA's registration review human health risk assessment for chlorpyrifos. While industry and public interest groups on both sides of this issue can debate what the recommendations mean and which recommendations should be followed, one thing should be clear to all persons following this issue: the science on this question is not resolved and would likely benefit from additional inquiry.

EPA has, however, been unable to persuade the 9th Circuit Court of

Appeals that further inquiry into this area of unsettled science should delay EPA's response to the Petition. Faced with an order requiring EPA to respond to the Petition, in October 2015, EPA chose to issue a proposed rule to revoke all chlorpyrifos tolerances based in part on the uncertain science surrounding neurodevelopmental toxicity suggested by certain epidemiology studies. The comments EPA has received on that proposal and on EPA's November 17, 2016 NODA suggest that there continue to be considerable areas of uncertainty with regard to what the epidemiology data show and deep disagreement over how those data should be considered in EPA's risk assessment.

Although not a legal consideration, it is important to recognize that for many decades chlorpyrifos has been and remains one of the most widely used pesticides in the United States, making any decision to retain or remove this pesticide from the market an extremely significant policy choice. In light of the significance of this decision and in light of the significant uncertainty that exists regarding the potential for chlorpyrifos to cause adverse neurodevelopmental effects, EPA's preference is to fully explore approaches raised by the SAP and commenters on the proposed rule, and possibly seek additional authoritative peer review of EPA's risk assessment prior to finalizing any regulatory action in the course of registration review. As the 9th Circuit has made clear in its August 12, 2016 order in PANNA v. EPA, EPA must provide a final response to the Petition by March 31, 2017, regardless of whether the science remains unsettled and irrespective of whatever options may exist for more a complete resolution of these issues during the registration review process.

While EPA acknowledges its obligation to respond to the Petition as required by the court, the court's order does not and cannot compel EPA to complete the registration review of chlorpyrifos in advance of the October 1, 2022 deadline provided in section 3(g) of FIFRA, 7 U.S.C. 136a(g). Although past EPA administrations had chosen to attempt to complete that review several years in advance of the statutory deadline (and respond to the Petition on the same time frame), it has turned out that it is not possible to fully address these issues early in the registration review period. As a result, EPA has concluded that it should alter its priorities and adjust the schedule for chlorpyrifos so that it can complete its review of the science addressing neurodevelopmental effects prior to making a final registration review

decision whether to retain, limit or remove chlorpyrifos from the market. Accordingly, EPA is denying these Petition claims and intends to complete a full and appropriate review of the neurodevelopmental data before either finalizing the proposed rule of October 30, 2015, or taking an alternative

regulatory path. EPA's denial of the Petition on the grounds provided above is wholly consistent with governing law. The petition provision in FFDCA section 408(d) does not address the timing for responding to this petition nor does it limit the extent to which EPA may coordinate its petition responses with the registration review provisions of FIFRA section 3(g). Further, provided EPA completes registration review by October 1, 2022, Congress otherwise gave the EPA Administrator the discretion to determine the schedule and timing for completing the review of the approximately over 1000 pesticide active ingredients currently subject to evaluation under section 3(g). EPA may lawfully re-prioritize the registration review schedule developed by earlier administrations provided that decision is consistent with law and an appropriate exercise of discretion. See Federal Communications Commission v. Fox Television Stations, 129 S.Ct. 1800 (2009) (Administrative Procedure Act does not require that a policy change be justified by reasons more substantial than those required to adopt a policy in the first instance). Nothing in FIFRA section 3(g) precludes EPĂ from altering a previously established registration review schedule. Given the absence of a clear statutory directive, FIFRA and the FFDCA provide EPA with discretion to take into account EPA's registration review of a pesticide in determining how and when the Agency responds to FFDCA petitions to revoke tolerances. As outlined above, given the importance of this matter and the fact that critical questions remain regarding the significance of the data addressing neurodevelopmental effects, EPA believes there is good reason to extend the registration review of chlorpyrifos and therefore to deny the Petition. To find otherwise would effectively give petitioners under the FFDCA the authority to re-order scheduling decisions regarding the FIFRA registration review process that Congress has vested in the Administrator.

10. Inhalation Exposure From Volatilization

a. Petitioners' claim. Petitioners assert that when EPA completed its 2006 OP CRA, EPA failed to consider and incorporate significant exposures to chlorpyrifos-contaminated air that exist for some populations in communities where chlorpyrifos is applied. Petitioners assert that these exposures exceeded safe levels when considering cholinesterase inhibition as a point of departure and that developmental neurotoxicity may occur at even lower exposure levels than those resulting in cholinesterase inhibition.

b. Agency response. To the extent petitioners are asserting that human exposure to chlorpyrifos spray drift and volatilized chlorpyrifos present neurodevelopmental risks for infants and children, EPA is denying this claim for the reasons stated above in our response to claims 7-9. As noted, EPA believes that, given the uncertainties associated with this identified risk concern, the appropriate course of action is for EPA to deny the Petition and work to further resolve this area of unsettled science in the time remaining for the completion of registration review under section 3(g) of FIFRA.

With respect to petitioners' claim that exposures to spray drift and volatilized chlorpyrifos present a risk from cholinesterase inhibition, EPA is denying the Petition for the reasons previously identified in EPA's Spray Drift Mitigation Decision of July 16, 2012 [EPA-HQ-OPP-2008-0850] and EPA's interim response of July 15, 2014 [EPA-HQ-OPP-2007-1005] addressing chlorpyrifos volatilization. In the Spray Drift Mitigation Decision, EPA determined that the chlorpyrifos registrants' adoption of label mitigation (in the form of label use rate reductions and no spray buffer zones) eliminated risk from cholinesterase inhibition as a result of spray drift. As for risks presented by volatilized chlorpyrifos that may occur following application, EPA's July 15, 2014 interim response to the Petition explained that recent vapor phase inhalation studies for both chlorpyrifos and chlorpyrifos-oxon made clear that neither vapor phase chlorpyrifos nor chlorpyrifos-oxon presents a risk of cholinesterase inhibition. Specifically, those studies, as indicated in EPA's memorandum, Chlorpyrifos: Reevaluation of the Potential Risks from Volatilization in Consideration of Chlorpyrifos Parent and Oxon Vapor Inhalation Toxicity Studies (Ref. 25), revealed that levels of chlorpyrifos and chlorpyrifos-oxon in vapor form are much lower than the levels seen in earlier aerosol studies that are better suited for evaluating spray drift. Indeed, no cholinesterase inhibition was observed in either volatility study. What is clear from these data is that the air cannot hold levels of

volatilized chlorpyrifos or its oxon that are capable of causing adverse effects from cholinesterase inhibition.

VI. Regulatory Assessment Requirements

As indicated previously, this action announces the Agency's order denying a petition filed, in part, under section 408(d) of FFDCA. As such, this action is an adjudication and not a rule. The regulatory assessment requirements applicable to rulemaking do not, therefore, apply to this action.

VII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

IX. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under FOR FURTHER INFORMATION CONTACT.

- The Petition from NRDC and PANNA and EPA's various responses to it are available in docket number EPA-HQ-OPP-2007-1005 available at http:// www.regulations.gov.
- FIFRA Scientific Advisory Panel (2016).
 "Chlorpyrifos: Analysis of Biomonitoring Data". Available at: https://
 www.epa.gov/sap/meeting-materials-april-19-21-2016-scientific-advisory-panel.
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 Response Characterization. August 21,
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 scipoly/sap/meetings/2008/september/
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- 7. U.S. EPA (2008). Transmittal of Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held September 16–18, 2008 on the Agency's Evaluation of the Toxicity Profile of Chlorpyrifos. Available at http://www.epa.gov/scipoly/sap/meetings/2008/september/sap0908report.pdf at 61.
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- Hofmann, J.N., Keifer, M.C., Furlong, C.E., De Roos, A.J., Farin., F.M., Fenske, R.A., van Belle, G., Checkoway, H. (2009) Serum Cholinesterase Inhibition in Relation to Paraoxonase-1 (PON1) Status among Organophosphate-Exposed Agricultural Pesticide Handlers./Environ Health Perspect 117:1402–1408 (2009). doi:10.1289/ehp.0900682. Available at http://dx.doi.org/ [Online 9 June 2009].
- 10. Eskenazi, B; Huen, K., Marks, A., Harley, K.G., Bradman, A., Boyd Barr, D., Holland, N. (2010) PON1 and Neurodevelopment in Children from the CHAMACOS Study Exposed to Organophosphate Pesticides in Utero. Environmental Health Perspectives. Vol. 118 (12): 1775–1781).
- 11. Harley KG, Huen K, Schall RA, Holland NT, Bradman A, et al.,(2011) Association of Organophosphate Pesticide Exposure and Paraoxonase with Birth Outcome in Mexican-American Women. PLoS ONE 6(8): e23923. doi:10.1371/journal.pone.0023923.
- 12. IPCS (International Programme on Chemical Safety) 2005. Chemical-Specific Adjustment Factors for Interspecies Differences and Human Variability: Guidance Document for Use of Data in Dose/Concentration-Response Assessment. Harmonization Project Document No. 2. World Health Organization, International Programme on Chemical Safety, Geneva, Switzerland.
- 13. U.S. EPA (2014). Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation. Available at https://www.epa.gov/risk/guidance-applying-quantitative-data-develop-data-derived-extrapolation-factors-interspecies-and.
- 14. For additional information on the Endocrine Disruptor Screening program see http://www.epa.gov/endo/.
- 15. For information related to the status of EDSP test orders/DCIs, status of EDSP OSRI: order recipient submissions and

- EPA responses, and other EDSP assay information see http://www.epa.gov/endo/pubs/toresources/index.htm.
- 16. For available Data Evaluation Records (DERs) for EDSP Tier 1, see https:// www.epa.gov/endocrine-disruption/ endocrine-disruptor-screening-programtier-1-screening-determinations-and.
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- 18. U.S. EPA (2005). Guidelines for Carcinogen Risk Assessment. Available at http://www.epa.gov/raf/publications/ pdfs/CANCER_GUIDELINES_FINAL_3-25-05.PDF.
- 19. Christenson, C. (2011). D388167, Chlorpyrifos Carcinogenicity: Review of Evidence from the U.S. Agricultural Health Study (AHS) Epidemiologic Evaluations 2003–2009.
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- 21. Zheng Q, Olivier K, Won YK, Pope CN. (2000). Comparative cholinergic neurotoxicity of oral chlorpyrifos exposures in pre-weaning and adult rats. Toxicological Sciences, 55(1): 124–132.
- 22. For additional information on the organophosphate cumulative risk assessment, see http://epa.gov/pesticides/cumulative/2006-op/op_cra_main.pdf.
- U.S. EPA (2011). Chlorpyrifos:
 Preliminary Human Health Risk
 Assessment for Registration. Available in
 docket number EPA—HQ—OPP—2008—
 0850, http://www.regulations.gov/
 #!documentDetail;D=EPA-HQ-OPP-2008 0850-0025.
- (23) For additional information on EPA's Harmonized Test Guidelines and international efforts at harmonization, see http://www.epa.gov/opp00001/science/guidelines.htm.
- (24) Available at http://www.regulations.gov in docket EPA-HQ-OPP-2008-0850.

Authority: 7 U.S.C. 136 *et seq.* and 21 U.S.C. 346a.

Dated: March 29, 2017.

E. Scott Pruitt,

Administrator.

[FR Doc. 2017–06777 Filed 4–4–17; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission,

Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (www.fmc.gov) or by contacting the Office of Agreements at (202)-523–5793 or tradeanalysis@fmc.gov.

Agreement No.: 010071–045. Title: Cruise Lines International Association Agreement.

Parties: A-Rosa Flussschiff GmbH; Acromas Shipping, Ltd./Saga Shipping; Aida Cruises; AMA Waterways; American Cruise Lines, Inc.; Aqua Expeditions Pte. Ltd.; Australian Pacific Touring Pty Ltd.; Avalon Waterways; Azamara Cruises; Carnival Cruise Lines; Celebrity Cruises, Inc.; Celestyal Cruises; Costa Cruise Lines; Compagnie Du Ponant; Croisieurope; Crystal Cruises; Cunard Line; Disney Cruise Line; Dream Cruises Management Ltd.; Emerald Waterways; French America Line; Hapag-Lloyd Kreuzfahrten Gmbh; Heritage River Journeys Pvt Ltd.; Holland America Line; Luftner Cruises; MSC Cruises; NCL Corporation; Oceania Cruises; P & O Cruises; P & O Cruises Australia; PandaW River Expeditions; Paul Gauguin Cruises; Pearl Seas Cruises; Princess Cruises; Pullmantur Cruises Ship Management Ltd.; Regent Seven Seas Cruises; Riviera Tours Ltd.; Royal Caribbean International; Scenic Luxury Cruises & Tours Ltd.; Seabourn Cruise Line; SeaDream Yacht Club; Shearings Holidays Ltd.; Silversea Cruises, Ltd.; Star Cruises (HK) Limited; St. Helena Line/Andrew Weir Shipping Ltd.; Tauck River Cruising; Thomson Cruises; Travelmarvel; Tui Cruises Gmbh; Uniworld River Cruises, Inc.; Venice Simplon-Orient-Express Ltd./ Belmond; and Windstar Cruises. Filing Party: Andre Picciurro, Esq.

Filing Party: Andre Picciurro, Esq. Kaye, Rose & Partners, LLP; Emerald Plaza, 402 West Broadway, Suite 1300; San Diego, CA 92101–3542.

Synopsis: The Amendment would update the Agreement membership and revise language in the Agreement regarding the election of the Chair and Vice Chair of the Agreement.

Agreement No.: 012476. Title: HSDG/HLAG/CMA CGM Slot Charter Agreement.

Parties: Hamburg Sud; Hapag-Lloyd AG; and CMA CGM S.A.

Filing Party: Wayne Rohde; Cozen O'Connor; 1200 19th Street NW., Washington, DC 20036.

Synopsis: The Agreement authorizes HSDG and HLAG to charter space to CMA CGM in the trade between the U.S. East Coast on the one hand, and Colombia, Ecuador, Peru and Chile on the other hand. The Parties have requested expedited review.

Agreement No.: 012477. Title: CMA CGM/HLAG U.S.-West Med Slot Charter Agreement. Parties: CMA CGM, S.A.; and Hapag

Lloyd AG.

Filing Party: Draughn B. Arbona, Esq; CMA CGM (America) LLC; 5701 Lake Wright Drive; Norfolk, VA 23502.

Synopsis: This Agreement authorizes CMA CGM to charter space to HLAG in the trade between Italy and Spain on the one hand, and the U.S. East Coast on the other hand.

Agreement No.: 012478. Title: NYK/OOCL Space Charter Agreement.

Parties: Nippon Yusen Kaisha and Orient Overseas Container Line Limited. Filing Party: Joshua P. Stein; Cozen

O'Connor; 1200 Nineteenth Street NW., Washington, DC 20036. Synopsis: The Agreement authorizes

NYK to charter space to OOCL on the service referred to as the PS1 and operated under THE Alliance Agreement (FMC Agreement No. 012439) and to enter into arrangements related to the chartering of such space.

By Order of the Federal Maritime Commission.

Dated: March 31, 2017.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2017–06734 Filed 4–4–17; 8:45 am]

BILLING CODE 6731-AA-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than April 21, 2017.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

UNITED STATES COURT OF APPEALS for the NINTH CIRCUIT

Office of the Clerk

After Opening a Case – Counseled Non-Immigration Agency Cases (revised April 2016)

Court Address – San Francisco Headquarters

Mailing Address for U.S. Postal Service	Mailing Address for Overnight Delivery (FedEx, UPS, etc.)	Street Address
Office of the Clerk James R. Browning Courthouse U.S. Court of Appeals P.O. Box 193939 San Francisco, CA 94119-3939	Office of the Clerk James R. Browning Courthouse U.S. Court of Appeals 95 Seventh Street San Francisco, CA 94103-1526	95 Seventh Street San Francisco, CA 94103

Court Addresses – Divisional Courthouses

Pasadena	Portland	Seattle
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$Court\ Website-\underline{www.ca9.uscourts.gov}$

The Court's website contains the Court's Rules and General Orders, information about electronic filing of documents, answers to frequently asked questions, directions to the courthouses, forms necessary to gain admission to the bar of the Court, opinions and memoranda, live streaming of oral arguments, links to practice manuals, and an invitation to join our Pro Bono Program.

Court Phone List

Main Phone Number	(415) 355-8000
Attorney Admissions	(415) 355-7800
Calendar Unit	(415) 355-8190
Docketing	(415) 355-7840
Death Penalty	(415) 355-8197
Electronic Filing – CM/ECF	
Library	(415) 355-8650
Mediation Unit	(415) 355-7900
Motions Attorney Unit	(415) 355-8020
Procedural Motions Unit	(415) 355-7860
Records Unit	(415) 355-7820
Divisional Court Offices: Pasadena Portland Seattle	(503) 833-5300

Electronic Filing - CM/ECF

The Ninth Circuit's CM/ECF (Case Management/Electronic Case Files) system is mandatory for all attorneys filing in this Court, unless they are granted an exemption. All non-exempted attorneys who appear in an ongoing case are required to register for and to use CM/ECF. Registration and information about CM/ECF is available on the Court's website at www.ca9.uscourts.gov under *Electronic Filing–CM/ECF*. Read the Circuit Rules, especially Ninth Circuit Rule 25-5, for guidance on filing documents electronically via CM/ECF, and see the CM/ECF User Guide for a complete list of the available types of filing events.

Rules of Practice

The Federal Rules of Appellate Procedure (Fed. R. App. P.), the Ninth Circuit Rules (9th Cir. R.) and the General Orders govern practice before this Court. The rules are available on the Court's website at www.ca9.uscourts.gov under *Rules*.

Practice Resources

The Appellate Lawyer Representatives' Guide to Practice in the United States Court of Appeals for the Ninth Circuit is available on the Court's website www.ca9.uscourts.gov at *Guides and Legal Outlines* > Appellate Practice Guide. The Court provides other resources in *Guides and Legal Outlines*.

Admission to the Bar of the Ninth Circuit

All attorneys practicing before the Court must be admitted to the Bar of the Ninth Circuit. Fed. R. App. P. 46(a); 9th Cir. R. 46-1.1 & 46-1.2.

For instructions on how to apply for bar admission, go to www.ca9.uscourts.gov and click on the *Attorneys* tab > *Attorney Admissions* > *Instructions*.

Notice of Change of Address

Counsel who are registered for CM/ECF must update their personal information, including street addresses and email addresses, online at: https://pacer.psc.uscourts.gov/pscof/login.jsf 9th Cir. R. 46-3.

Counsel who have been granted an exemption from using CM/ECF must file a written change of address with the Court. 9th Cir. R. 46-3.

Payment of Fees

The \$500.00 filing fee or a motion to proceed in forma pauperis shall accompany the petition. 9th Cir. R. 3-1.

A motion to proceed in forma pauperis must be supported by the affidavit of indigency found at Form 4 of the Federal Rules of Appellate Procedure, available at the Court's website, www.ca9.uscourts.gov, under *Forms*.

Failure to satisfy the fee requirement or to apply to proceed without payment of fees will result in the petition's dismissal. 9th Cir. R. 42-1.

Motions Practice

Following are some of the basic points of motion practice, governed by Fed. R. App. P. 27 and 9th Cir. R. 27-1 through 27-14.

- Neither a notice of motion nor a proposed order is required. Fed. R. App. P. 27(a)(2)(C)(ii), (iii).
- Motions may be supported by an affidavit or declaration. 28 U.S.C. § 1746.
- Each motion should provide the position of the opposing party. Circuit Advisory Committee Note to Rule 27-1(5); 9th Cir. R. 31-2.2(b)(6).
- A response to a motion is due 10 days from the service of the motion. Fed. R. App. P. 27(a)(3)(A); Fed. R. App. P. 26(c). The reply is due 7 days from service of the response. Fed. R. App. P. 27(a)(4); Fed. R. App. P. 26(c).
- A response requesting affirmative relief must include that request in the caption. Fed. R. App. P. 27(a)(3)(B).
- A motion filed after a case has been scheduled for oral argument, has been argued, is under submission or has been decided by a panel, must include on the initial page and/or cover the date of argument, submission or decision and, if known, the names of the judges on the panel. 9th Cir. R. 25-4.

Emergency or Urgent Motions

All emergency and urgent motions must conform with the provisions of 9th Cir. R. 27-3. Note that a motion requesting procedural relief (e.g., an extension of time to file a brief) is *not* the type of matter contemplated by 9th Cir. R. 27-3. Circuit Advisory Committee Note to 27-3(3).

Prior to filing an emergency motion, the moving party *must* contact an attorney in the Motions Unit in San Francisco at (415) 355-8020.

When it is absolutely necessary to notify the Court of an emergency outside of standard office hours, the moving party shall call (415) 355-8000. Keep in mind that this line is for true emergencies that cannot wait until the next business day (e.g., an imminent execution or removal from the United States).

Briefing Schedule

The Court sets the briefing schedule at the time the petition is docketed.

Certain motions (e.g., a motion for dismissal) automatically stay the briefing schedule. 9th Cir. R. 27-11.

The opening and answering brief due dates are not subject to the additional time described in Fed. R. App. P. 26(c). 9th Cir. R. 31-2.1. The early filing of petitioner's opening brief does not advance the due date for respondent's answering brief. *Id*.

Extensions of Time to file a Brief

Streamlined Request

Subject to the conditions described at 9th Cir. R. 31-2.2(a), you may request one streamlined extension of up to 30 days from the brief's existing due date. Submit your request via CM/ECF using the "File Streamlined Request to Extend Time to File Brief" event on or before your brief's existing due date. No form or written motion is required.

Written Extension

Requests for subsequent extensions or extensions of more than 30 days will be granted only upon a written motion supported by a showing of diligence and substantial need. This motion shall be filed at least 7 days before the due date for the brief. The motion shall be accompanied by an affidavit or declaration that includes all of the information listed at 9th Cir. R. 31-2.2(b).

The Court will ordinarily adjust the schedule in response to an initial motion. Circuit Advisory Committee Note to Rule 31-2.2. The Court expects that the brief will be filed within the requested period of time. *Id*.

Contents of Briefs and Record

The required components of a brief are set out at Fed. R. App. P. 28 and 32, and 9th Cir. R. 28-2, 32-1 and 32-2.

The content and filing of the record are governed by Fed. R. App. P. 16(a) and 17. If respondent does not file the record or certified list by the specified date, petitioner may move to amend the briefing schedule.

After the electronically submitted brief has been reviewed, the Clerk will request 7 paper copies of the brief that are identical to the electronic version. 9th Cir. R. 31-1. Do not submit paper copies until directed to do so.

Excerpts of Record

The Court requires Excerpts of Record rather than an Appendix. 9th Cir. R. 30-1.1. Please review 9th Cir. R. 17-1.3 through 17-1.6 to see a list of the specific contents and format. For Excerpts that exceed 75 pages, the first volume must comply with 9th Cir. R. 17-1.6 and 30-1.6(a). Excerpts exceeding 300 pages must be filed in multiple volumes. 9th Cir. R. 30-1.6(a).

Respondent may file supplemental Excerpts, and petitioner may file further Excerpts. 9th Cir. R. 17-1.7; 17-1.8; 30-1.7 and 30-1.8. If you are a respondent responding to a pro se brief that did not come with Excerpts, then your Excerpts need only include the contents set out at 9th Cir. R. 30-1.7.

Excerpts must be submitted in PDF format in CM/ECF on the same day the filer submits the brief. The filer shall serve a paper copy of the Excerpts on any party not registered for CM/ECF.

If the Excerpts contain sealed materials, you must submit the sealed documents electronically in a separate volume in a separate transaction from the unsealed volumes, along with a motion to file under seal. 9th Cir. R. 27-13(e). Sealed filings must be served on all parties by mail, or if mutually agreed by email, rather than through CM/ECF noticing.

After electronic submission, the Court will direct the filer to file 4 separately-bound paper copies of the excerpts of record with white covers.

Mediation Program

Mediation Questionnaires are required in all counseled agency cases except those cases seeking review of a Board of Immigration Appeals decision. 9th Cir. R.

15-2.

The Mediation Questionnaire is available on the Court's website at www.ca9.uscourts.gov under *Forms*. The Mediation Questionnaire should be filed within 7 days of the docketing of the petition. The Mediation Questionnaire is used only to assess settlement potential.

If you are interested in requesting a conference with a mediator, you may call the Mediation Unit at (415) 355-7900, email ca09_mediation@ca9.uscourts.gov or make a written request to the Chief Circuit Mediator. You may request conferences confidentially. More information about the Court's mediation program is available at http://www.ca9.uscourts.gov/mediation.

Oral Hearings

Approximately 14 weeks before a case is set for oral hearing, the parties are notified of the hearing dates and locations and are afforded 3 days from the date of those notices to inform the Court of any conflicts. Notices of the actual calendars are then distributed approximately 10 weeks before the hearing date.

The Court will change the date or location of an oral hearing only for good cause, and requests to continue a hearing filed within 14 days of the hearing will be granted only upon a showing of exceptional circumstances. 9th Cir. R. 34-2.

Oral hearing will be conducted in all cases unless all members of the panel agree that the decisional process would not be significantly aided by oral argument. Fed. R. App. P. 34(a)(2).

Oral arguments are live streamed to You Tube and can be accessed on the Court's website.

Ninth Circuit Appellate Lawyer Representatives APPELLATE MENTORING PROGRAM

1. Purpose

The Appellate Mentoring Program is intended to provide mentoring on a voluntary basis to attorneys who are new to federal appellate practice or would benefit from guidance at the appellate level. In addition to general assistance regarding federal appellate practice, the project will provide special focus on two substantive areas of practice - immigration law and habeas corpus petitions. Mentors will be volunteers who have experience in immigration, habeas corpus, and/or appellate practice in general. The project is limited to counseled cases.

2. Coordination, recruitment of volunteer attorneys, disseminating information about the program, and requests for mentoring

Current or former Appellate Lawyer Representatives (ALRs) will serve as coordinators for the Appellate Mentoring Program. The coordinators will recruit volunteer attorneys with appellate expertise, particularly in the project's areas of focus, and will maintain a list of those volunteers. The coordinators will ask the volunteer attorneys to describe their particular strengths in terms of mentoring experience, substantive expertise, and appellate experience, and will maintain a record of this information as well.

The Court will include information about the Appellate Mentoring Program in the case opening materials sent to counsel and will post information about it on the Court's website. Where appropriate in specific cases, the Court may also suggest that counsel seek mentoring on a voluntary basis.

Counsel who desire mentoring should contact the court at mentoring@ca9.uscourts.gov, and staff will notify the program coordinators. The coordinators will match the counsel seeking mentoring with a mentor, taking into account the mentor's particular strengths.

3. The mentoring process

The extent of the mentor's guidance may vary depending on the nature of the case, the mentee's needs, and the mentor's availability. In general, the mentee should initiate contact with the mentor, and the mentee and mentor should determine together how best to proceed. For example, the areas of guidance may range from

basic questions about the mechanics of perfecting an appeal to more sophisticated matters such as effective research, how to access available resources, identification of issues, strategy, appellate motion practice, and feedback on writing.

4. Responsibility/liability statement

The mentee is solely responsible for handling the appeal and any other aspects of the client's case, including all decisions on whether to present an issue, how to present it in briefing and at oral argument, and how to counsel the client. By participating in the program, the mentee agrees that the mentor shall not be liable for any suggestions made. In all events, the mentee is deemed to waive and is estopped from asserting any claim for legal malpractice against the mentor.

The mentor's role is to provide guidance and feedback to the mentee. The mentor will not enter an appearance in the case and is not responsible for handling the case, including determining which issues to raise and how to present them and ensuring that the client is notified of proceedings in the case and receives appropriate counsel. The mentor accepts no professional liability for any advice given.

5. Confidentiality statement

The mentee alone will have contact with the client, and the mentee must maintain client confidences, as appropriate, with respect to non-public information.

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United States Court of Appeals for the Ninth Circuit

#.O. Box 31478 Billings, Montana 59107-1478

CHAMBERS OF SIDNEY R. THOMAS CHIEF JUDGE

December 1, 2014

Tel: (406) 373-3200 Fax: (406) 373-3250

Dear Counsel:

I want to take this opportunity to introduce you to the Court's mediation program. The court offers you and your clients professional mediation services, at no cost, to help resolve disputes quickly and efficiently and to explore the development of more satisfactory results than can be achieved from continued litigation. Each year the mediators facilitate the resolution of hundreds of cases, from the most basic contract and tort actions to the most complex cases involving multiple parties, numerous pieces of litigation and important issues of public policy.

The eight circuit mediators, all of whom work exclusively for the court, are highly experienced attorneys from a variety of practices; all have extensive training and experience in negotiation, appellate mediation, and Ninth Circuit practice and procedure. Although the mediators are court employees, the Court has adopted strict confidentiality rules and practices to ensure that what goes on in mediation stays in mediation. *See* Circuit Rule 33-1.

The first step in the mediation process is case selection. To assist the mediators in the case selection process, appellants/petitioners must file a completed Mediation Questionnaire within 7 days of the docketing of the case. *See* Circuit Rules 3-4, and 15-2. Appellees may also fill out and file a questionnaire. The questionnaire with filing instructions accompanies this letter and is also available at www.ca9.uscourts.gov/mediation/forms.php. All counsel are also invited to submit, by e-mail to ca09_mediation@ca9.uscourts.gov, additional, confidential information that might assist the mediators in the case selection process.

Page 2

In most cases, the mediator will schedule a settlement assessment conference, with counsel only, to determine whether the case is suitable for mediation. Please be assured that participation in the mediation program will not slow down disposition of your appeal. Mediation discussions are not limited to the issues on appeal. The discussions can involve other cases and may include individuals who are not parties to the litigation, if doing so enables the parties to reach a global settlement.

Further information about the mediation program may be found on the court's website: www.ca9.uscourts.gov/mediation/. Please address questions directly to the Mediation Unit at 415-355-7900 or ca09mediation@ca9.uscourts.gov.

Our mediators do a terrific job. I hope you'll give them the opportunity to work on your case.

Sincerely,

Sidney R. Thomas Chief Circuit Judge

Sidney R Momas

Case: 17-71636, 06/05/2017, ID: 10460406, DktEntry: 1-4, Page 1 of 2

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Circuit Mediation Office
Phone (415) 355-7900 Fax (415) 355-8566
http://www.ca9.uscourts.gov/mediation

MEDIATION QUESTIONNAIRE

This form is available in a fillable version at http://cdn.ca9.uscourts.gov/datastore/uploads/forms/Mediation Questionnaire.pdf.

The purpose of this questionnaire is to help the court's mediators provide the best possible mediation service in this case; it serves no other function. Responses to this questionnaire are *not* confidential. Appellants/Petitioners must electronically file this document within 7 days of the docketing of the case. 9th Cir. R. 3-4 and 15-2. Appellees/Respondents may file the questionnaire, but are not required to do so.

9th Circuit Case Number(s):
District Court/Agency Case Number(s):
District Court/Agency Location:
Case Name: v.
If District Court, docket entry number(s) of order(s) appealed from:
Name of party/parties submitting this form:
Briefly describe the dispute that gave rise to this lawsuit.
Briefly describe the result below and the main issues on appeal.

(Continue to next page)

Case: 17-71636, 06/05/2017, ID: 10460406, DktEntry: 1-4, Page 2 of 2

Describe any proceedings remaining below or any related proceedings in other tribunals.
Describe any proceedings remaining below of any related proceedings in other tribunals.
Provide any other thoughts you would like to bring to the attention of the mediator.
Any party may provide additional information in confidence directly to the Circuit Mediation Office at ca09_mediation@ca9.uscourts.gov. Provide the case name and Ninth Circuit case number in your message. Additional information might include level of interest in including this case in the mediation program, the case's settlement history, issues beyond the litigation that the parties might address in a settlement context, or future events that might affect the parties' willingness or ability to mediate the case.
CERTIFICATION OF COUNSEL
I certify that:
a current service list with telephone and fax numbers and email addresses is attached (see 9th Circuit Rule 3-2).
I understand that failure to provide the Court with a completed form and service list may result in sanctions, including dismissal of the appeal.
Signature
("s/" plus attorney name may be used in lieu of a manual signature on electronically-filed documents.)
Counsel for

How to File: Complete the form and then convert the filled-in form to a static PDF (File > Print > PDF Printer or any PDF Creator). To file, log into Appellate ECF and select File Mediation Questionnaire. (*Use of the Appellate ECF system is mandatory for all attorneys filing in this Court, unless they are granted an exemption from using the system*.)

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Office of the Clerk United States Court of Appeals for the Ninth Circuit

Post Office Box 193939 San Francisco, California 94119-3939 415-355-8000

Molly C. Dwyer Clerk of Court

June 05, 2017

No.: 17-71636

Short Title: LULAC, et al v. Scott Pruitt, et al

Dear Petitioners/Counsel

Your Petition for Review has been received in the Clerk's office of the United States Court of Appeals for the Ninth Circuit. The U.S. Court of Appeals docket number shown above has been assigned to this case. You must indicate this Court of Appeals docket number whenever you communicate with this court regarding this case.

The due dates for filing the parties' briefs and otherwise perfecting the petition have been set by the enclosed "Time Schedule Order," pursuant to applicable FRAP rules. These dates can be extended only by court order. Failure of the petitioner to comply with the time schedule order will result in automatic dismissal of the petition. 9th Cir. R. 42-1.

UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

FILED

JUN 05 2017

MOLLY C. DWYER, CLERK U.S. COURT OF APPEALS

LEAGUE OF UNITED LATIN AMERICAN CITIZENS; PESTICIDE ACTION NETWORK NORTH AMERICA; NATURAL RESOURCES DEFENSE COUNCIL; CALIFORNIA RURAL LEGAL ASSISTANCE FOUNDATION; FARMWORKERS ASSOCIATION OF FLORIDA; FARMWORKER JUSTICE GREENLATINOS; LABOR COUNCIL FOR LATIN AMERICAN ADVANCEMENT; LEARNING DISABILITIES ASSOCIATION OF AMERICA; NATIONAL HISPANIC MEDICAL ASSOCIATION: PINEROS Y CAMPESINOS UNIDOS DEL NOROESTE; UNITED FARM WORKERS,

Petitioners,

V.

SCOTT PRUITT, Administrator of United States Environmental Protection Agency; U.S. ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

No. 17-71636

EPA No.

Environmental Protection Agency

TIME SCHEDULE ORDER

The parties shall meet the following time schedule.

Case: 17-71636, 06/05/2017, ID: 10460406, DktEntry: 1-5, Page 3 of 3

Mon., June 12, 2017 Mediation Questionnaire due. If your registration for

Appellate ECF is confirmed after this date, the Mediation Questionnaire is due within one day of receiving the email from PACER confirming your

registration.

Thu., August 24, 2017 Petitioners' opening brief and excerpts of record shall

be served and filed pursuant to FRAP 32 and 9th Cir.

R. 32-1.

Mon., September 25, 2017 Respondents' answering brief and excerpts of record

shall be served and filed pursuant to FRAP 32 and

9th Cir. R. 32-1.

The optional petitioners' reply brief shall be filed and served within 21 days of service of the respondents' brief, pursuant to FRAP 32 and 9th Cir. R. 32-1.

Failure of the petitioners to comply with the Time Schedule Order will result in automatic dismissal of the appeal. See 9th Cir. R. 42-1.

FOR THE COURT:

MOLLY C. DWYER CLERK OF COURT

By: Bradley Ybarreta

Deputy Clerk

Ninth Circuit Rule 27-7