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17 **UNITED STATES DISTRICT COURT**  
18 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**

19 ALIANZA NACIONAL de )  
20 CAMPESINAS, *et al.*, )

21 *Plaintiffs,* )

22 v. )

23 UNITED STATES ENVIRONMENTAL )  
24 PROTECTION AGENCY, *et al.*, )

25 *Defendants.* )

26 CROPLIFE AMERICA, )

27 *Intervenor-* )  
28 *Defendant* )

Civ. No. 4:22-cv-09030-JST

District Judge Jon S. Tigar  
Magistrate Judge Thomas S. Hixson

**PARTIAL CONSENT DECREE**

1 **PARTIAL CONSENT DECREE**

2 WHEREAS, in 1996, Congress passed the Food Quality Protection Act (“FQPA”), that  
3 amended the Federal Food, Drug, and Cosmetic Act (“FFDCA”);

4 WHEREAS, FFDCA section 408(p)(1), 21 U.S.C. § 346a(p)(1), requires the United  
5 States Environmental Protection Agency (“EPA”) to develop an estrogenic substances screening  
6 program “to determine whether certain substances may have an effect in humans that is similar to  
7 an effect produced by a naturally occurring estrogen, or such other endocrine effect as the EPA  
8 Administrator may designate;”

9 WHEREAS, FFDCA section 408(p)(2), 21 U.S.C. § 346a(p)(2), requires EPA to  
10 implement the estrogenic substances screening program;

11 WHEREAS, FFDCA section 408(p)(3)(a), 21 U.S.C. § 346a(p)(3)(a), requires EPA to  
12 “provide for the testing of all pesticide chemicals” in carrying out the program;

13 WHEREAS, under section 408(p)(6) of the FFDCA, 21 U.S.C. § 346a(p)(6), if a  
14 substance is found “to have an endocrine effect on humans, [EPA] shall, as appropriate, take  
15 action under such statutory authority as is available to [EPA], including consideration under  
16 other sections of this chapter, as is necessary to ensure the protection of public health;”

17 WHEREAS, in 1998, EPA developed and began implementing the Endocrine Disruptor  
18 Screening Program (“EDSP”);

19 WHEREAS, on December 20, 2022, Alianza Nacional de Campesinas, Pesticide Action  
20 Network North America, Rural Coalition, Center for Environmental Health, Organización en  
21 California de Líderes Campesinas, and Center for Food Safety (“Plaintiffs”) filed a complaint in  
22 the U.S. District Court for the Northern District of California against EPA and Michael S. Regan  
23 in his official capacity as EPA Administrator for declaratory and injunctive relief, captioned  
24 *Alianza Nacional de Campesinas, et al. v. United States Environmental Protection Agency, et al.*,  
25 Case No. 4:23-cv-09030-JST;

26 WHEREAS, CropLife America intervened in the case;

1 WHEREAS, Plaintiffs allege that EPA failed to undertake certain non-discretionary  
2 duties under section 408(p) of the FFDCA, 21 U.S.C. § 346a(p), and that such alleged failure is  
3 actionable under the Administrative Procedure Act (“APA”), 5 U.S.C. § 702;

4 WHEREAS, the relief requested in the complaint includes, among other things, an order  
5 from this Court to establish a date certain by which EPA must fulfill its mandatory duties, *see*  
6 *Compl. at 53 (Dkt. No. 1)*;

7 WHEREAS, on October 27, 2023, EPA issued a notice in the Federal Register setting  
8 forth the agency’s near-term strategies for implementing the EDSP (“Near-Term Strategies  
9 Document”), *see* 88 Fed. Reg. 73841 (Oct. 27, 2023);

10 WHEREAS, subject to the terms set forth herein, Plaintiffs and EPA (“Settling Parties”)  
11 wish to resolve by settlement the case, without any admission of any fact or issue of law;

12 WHEREAS, Plaintiffs and EPA, by entering into this Partial Consent Decree (“Consent  
13 Decree”), do not waive or limit any claim, remedy, or defense, on any grounds, related to any  
14 final EPA action;

15 WHEREAS, it is in the interest of the public, Plaintiffs, EPA, and judicial economy to  
16 resolve this matter without protracted litigation;

17 WHEREAS, Plaintiffs and EPA agree that this Court has jurisdiction over the matters  
18 resolved in this Consent Decree pursuant to the APA, 5 U.S.C. § 702, and that venue is proper in  
19 the Northern District of California pursuant to 28 U.S.C. § 1391(e) and Civil L.R. 3-2(c)–(d);

20 WHEREAS, the scope of the obligations set forth in Paragraphs 1 and 2 of this Consent  
21 Decree relate solely to the conventional pesticide active ingredients identified in the “List of  
22 Conventional Registration Review Chemicals for Which an FFDCA Section 408(p)(6)  
23 Determination is Needed,” (“Section 408(p)(6) List”), attached as Reference 2 to the Near-Term  
24 Strategies Document, 88 Fed. Reg. at 73842, Ref. 2;

25 WHEREAS, the Parties intend to reserve resolution of Plaintiffs’ claim for fees and costs  
26 until after execution of this Consent Decree, consistent with the terms herein;

1 WHEREAS, this Consent Decree constitutes a complete and final settlement (i.e., is in  
2 full satisfaction) of claims asserted by Plaintiffs in this case concerning certain EPA actions in  
3 implementing and carrying out the EDSP, as specifically defined below as the “Covered Matter,”  
4 and all claims that Plaintiffs could have asserted with respect to the allegations in this case  
5 regarding the Covered Matter;

6 WHEREAS, the Parties are concurrently entering an out-of-court partial settlement  
7 agreement (“Settlement Agreement”) resolving Plaintiffs’ claims in this case as to EPA’s  
8 discretionary duties;

9 WHEREAS, the Court, by entering this Consent Decree, finds that the Consent Decree is  
10 fair, reasonable, in the public interest, and consistent with the FFDCA and APA; and

11 NOW, THEREFORE, before the taking of testimony, without trial or determination of  
12 any issues of fact or law, and upon the consent of Plaintiffs and Defendant EPA, it is hereby  
13 ordered, adjudged, and decreed that:

14 1. FFDCA Section 408(p)(5) Test Orders: For a period of five years from the  
15 effective date of the Consent Decree, if in the scheduled Federal Insecticide, Fungicide, and  
16 Rodenticide Act (“FIFRA”) registration review process for a conventional pesticide active  
17 ingredient on the Section 408(p)(6) List EPA has: (a) explicitly determined that there are FFDCA  
18 section 408(p) data needs for assessing the conventional pesticide active ingredient’s potential  
19 for adverse effects to the estrogen pathways in humans and (b) explicitly identified a timeframe  
20 for issuing a FIFRA data call-in (“DCI”) to obtain such data, but at least 90 days have passed  
21 since Plaintiffs notified EPA that the FIFRA DCI was not timely issued and EPA has not yet  
22 issued the FIFRA DCI, then EPA will issue a FFDCA section 408(p)(5) test order within 90 days  
23 after receiving clearance from the Office of Management and Budget of the FFDCA section  
24 408(p)(5) test order(s) for the particular conventional pesticide active ingredient.

25 2. FIFRA Registration Review: For a period of five years from the effective date of  
26 the Consent Decree, concurrent with or prior to any proposed final registration review decision  
27 document for a conventional pesticide active ingredient on the Section 408(p)(6) List, EPA will  
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1 develop a document that can be appended to registration review documents, in which the Agency  
2 includes clear statements confirming that EPA has sufficient data to assess the conventional  
3 pesticide active ingredient’s potential for adverse effects to the estrogen pathway in humans to  
4 make the FFDCA section 408(p) data decision. If EPA determines that an estrogen-related effect  
5 is the most sensitive endpoint for the pesticide, EPA will address its FFDCA section 408(p)  
6 commitment by explaining in the appendix how it is regulating to protect against that effect.

7 3. FIFRA New Registration Applications: For a period of five years from the  
8 effective date of the Consent Decree, for each new conventional pesticide active ingredient  
9 application received, EPA will either require such application to be supported by appropriate  
10 data sufficient for assessing potential impact on estrogen pathway, such as an acceptable 2-  
11 generation reproductive toxicity study performed under the current guideline, or other  
12 scientifically relevant information or will issue an order exempting the conventional pesticide  
13 new active ingredient from FFDCA section 408(p) testing because the new active ingredient, is  
14 “anticipated not to produce any effect in humans similar to an effect produced by a naturally  
15 occurring estrogen.” In its registration-related decision memoranda for each new conventional  
16 pesticide active ingredient, the Agency will include clear statements confirming that EPA has  
17 sufficient data to assess the conventional pesticide active ingredient’s potential for adverse  
18 effects to the estrogen pathway in humans to make the FFDCA section 408(p) data decision or  
19 will publish the exemption order. If EPA determines that an estrogen-related effect is the most  
20 sensitive endpoint for the pesticide, EPA will address its FFDCA section 408(p) commitment by  
21 explaining in the memo how it is regulating to protect against that effect.

22 4. Implementation: EPA shall implement the EDSP no later than 10 years from the  
23 effective date of this Consent Decree. For purposes of this paragraph, “implement” means EPA  
24 shall make Section 408(p) data decisions, require any further needed testing, and make FFDCA  
25 Section 408(p)(6) determinations for human estrogen effects for those chemicals identified in  
26 Table 1 of the Section 408(p)(6) List that EPA concludes are supported by “appropriate validated  
27 test systems and other scientifically relevant information.” 21 U.S.C. § 346a(p)(1). At the time  
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1 of the execution of this Decree, EPA considers the 2-generation reproductive toxicity study using  
2 the current guideline and an extended one-generation reproductive toxicity study using the  
3 guideline produced by the Organization for Economic Cooperation and Development (TG443) to  
4 be appropriate validated test systems.

5       5.     Termination: After EPA has completed the actions set forth in Paragraphs 1  
6 through 4 of this Consent Decree, and the issue of costs of litigation (including reasonable  
7 attorneys' fees) has been resolved, EPA may move to have this Consent Decree terminated.  
8 Plaintiffs shall have 14 days to respond to such motion, unless the parties stipulate to a longer  
9 time for Plaintiffs to respond.

10       6.     Modification of Deadlines: The deadlines established by this Consent Decree may  
11 be extended (a) by written stipulation of Plaintiffs and EPA with notice to the Court, or (b) by the  
12 Court upon motion of EPA for good cause shown pursuant to the Federal Rules of Civil  
13 Procedure and upon consideration of any responses by Plaintiffs and any reply by EPA. Any  
14 other provision of this Consent Decree may also be modified by the Court following motion of  
15 an undersigned party for good cause shown pursuant to the Federal Rules of Civil Procedure and  
16 upon consideration of any response by a non-moving party and any reply.

- 17           i.    If EPA anticipates failing to meet a deadline in this Agreement, EPA shall provide  
18 written notice, via electronic mail or other means, to the other Parties as soon as  
19 practicable before the deadline arises. Within 30 days of receipt of the written  
20 notice, the Parties shall meet and confer to discuss when the commitment can be  
21 expected to be fulfilled following the delay and whether deadlines should be  
22 modified to avoid a breach.

23       7.     Covered Matter: "Covered Matter" as used in this Consent Decree means EPA's  
24 duties to (a) implement an estrogenic substances screening program; (b) "provide for the testing  
25 of all pesticide chemicals" in carrying out the program; and (c) and, if a substance is found "to  
26 have an endocrine effect on humans, . . . as appropriate, take action under such statutory  
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1 authority as is available to [EPA], . . . as is necessary to ensure the protection of public health,”  
2 *see* 21 U.S.C. § 346a(p)(2), (3)(a), (6).

3 8. Lapse in Appropriations: If a lapse in appropriations occurs within 120 days prior  
4 to a deadline in this Consent Decree, that deadline shall be extended automatically one day for  
5 each day of the lapse in appropriations. Nothing in this Paragraph shall preclude EPA from  
6 seeking an additional extension of time through modification of this Consent Decree pursuant to  
7 Paragraph 6.

8 9. Dispute Resolution: In the event of a dispute between Plaintiffs and EPA  
9 concerning the interpretation or implementation of any aspect of this Consent Decree, the  
10 disputing party shall provide the other party with written notice, via electronic mail or other  
11 means, outlining the nature of the dispute and requesting informal negotiations. The parties shall  
12 meet and confer in order to attempt to resolve the dispute. If the parties are unable to resolve the  
13 dispute within 30 days after receipt of the notice, either party may petition the Court to resolve  
14 the dispute.

- 15 i. No motion or other proceeding seeking to enforce this Consent Decree or for  
16 contempt of Court shall be properly filed unless the procedure set forth in  
17 Paragraph 9 has been followed, and the moving party has provided the other party  
18 with written notice, via electronic mail or other means, received at least 10  
19 business days before the filing of such motion or proceeding.

20 10. Attorneys' Fees: The deadline for filing a motion for costs of litigation (including  
21 attorneys' fees) for activities performed prior to entry of this Consent Decree is hereby extended  
22 until 90 days after this Consent Decree is entered by the Court. During this period, the parties  
23 shall seek to resolve any claim for costs of litigation (including attorneys' fees) or a stipulation or  
24 motion to extend the deadline to file such a motion. EPA reserves the right to oppose any such  
25 request. The Court shall retain jurisdiction to resolve any request for costs of litigation,  
26 including attorneys' fees.

1 i. Plaintiffs reserve the right to seek additional costs of litigation (including  
2 reasonable attorneys' fees) incurred subsequent to entry of this Consent Decree.

3 EPA reserves the right to oppose any such request for additional costs of litigation  
4 (including attorneys' fees).

5 11. Judicial Enforcement: This Court shall retain jurisdiction over this matter to  
6 enforce the terms of this Consent Decree and to consider any requests for costs of litigation  
7 (including attorneys' fees).

8 12. Agency Discretion: Nothing in this Consent Decree shall be construed to limit or  
9 modify any discretion accorded to EPA by the FFDCA or by general principles of administrative  
10 law in taking the actions which are the subject of this Consent Decree, including the discretion to  
11 alter, amend, or revise any final actions taken pursuant to this Consent Decree. EPA's obligation  
12 to perform each action specified in this Consent Decree does not constitute a limitation or  
13 modification of EPA's discretion within the meaning of this Paragraph.

14 13. No Admission of Liability: Except as expressly set forth herein, nothing in this  
15 Consent Decree shall be construed as an admission of any issue of fact or law nor to waive or  
16 limit any claim, remedy, or defense, on any grounds, related to any final action EPA takes with  
17 respect to the actions addressed in the Consent Decree.

18 14. Drafting: It is hereby expressly understood that this Consent Decree was jointly  
19 drafted by Plaintiffs and EPA. Accordingly, the parties hereby agree that any and all rules of  
20 construction to the effect that ambiguity is construed against the drafting party shall be  
21 inapplicable in any dispute concerning the terms, meaning, or interpretation of this Consent  
22 Decree.

23 15. Public Notice and Comment: The Parties agree and acknowledge that before this  
24 proposed Consent Decree can be finalized and entered by the Court, EPA shall provide notice of  
25 the proposed Consent Decree in the *Federal Register* and an opportunity for public comment.  
26 After this proposed Consent Decree has undergone notice and comment, the EPA Administrator  
27 and/or the Attorney General, as appropriate, shall promptly consider any written comments in  
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1 determining whether to withdraw or withhold their consent to the proposed Consent Decree. If  
2 the EPA Administrator and/or the Attorney General do not elect to withdraw or withhold  
3 consent, EPA shall promptly execute the final Consent Decree.

4 16. Notice: Any notice required or made with respect to this Agreement shall be in  
5 writing and shall be effective upon receipt. Any notice or other documents required pursuant to  
6 this Agreement shall be sent via email to the following contact persons:

7 For Plaintiffs:

8 Sylvia Wu,  
9 Center for Food Safety  
10 300 California Street, Suite 12-013  
11 San Francisco, CA 94108  
12 Phone: (415) 826-2770  
13 swu@centerforfoodsafety.org

14 For EPA:

15 Chief, Environmental Defense Section  
16 U.S. Department of Justice  
17 Environment & Natural Resources Division  
18 P.O. Box 7611  
19 Washington, D.C. 20044  
20 Phone: (202) 514-2219  
21 Fax: (202) 514-8865

22 Lucy Brown  
23 U.S. Department of Justice/ENRD  
24 Environmental Defense Section  
25 P.O. Box 7611  
26 Washington, D.C. 20004-7611  
27 Phone: (202) 598-1868  
28 lucy.e.brown@usdoj.gov

Amber Aranda  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460  
WJCN 7507, Mail Code 2333A  
Phone: (202) 564-1737  
aranda.amber@epa.gov

1 Upon written notice to the other Parties, any party may designate a successor contact person for  
2 any matter relating to this Agreement.

3 17. Anti-Deficiency Act: Any obligations of EPA to expend funds under this Consent  
4 Decree are subject to the availability of appropriations in accordance with the Anti-Deficiency  
5 Act, 31 U.S.C. § 1341. This Consent Decree shall not be construed to require EPA to obligate or  
6 pay funds in contravention of the Anti-Deficiency Act, 31 U.S.C. § 1341, or any other applicable  
7 provision of law.

8 18. Force Majeure: The possibility exists that circumstances outside the reasonable  
9 control of EPA could delay compliance with the provisions of this Consent Decree. Such  
10 circumstances include, but are not limited to, the unavailability of appropriated funds for  
11 expenditure, government shutdown, and other significant, unforeseen events that require an  
12 immediate and/or time-consuming response by EPA. By “significant, unforeseen events,” the  
13 Parties mean events outside of EPA’s control and that are not anticipated in, or part of, EPA’s  
14 existing obligations, operations, and activities. Should a delay occur due to such circumstances,  
15 EPA shall act in good faith and will exert all reasonable efforts to expeditiously attain  
16 compliance with this Consent Decree. EPA shall provide Plaintiffs with reasonable notice within  
17 20 days of becoming aware of such a delay, and will specifically provide in writing the cause of  
18 the delay and the actions EPA will take to resolve the delay. Any dispute regarding invocation  
19 of this provision shall be resolved in accordance with the Dispute Resolution provisions of  
20 Paragraph 9.

21 19. Voidability: If for any reason the Court should decline to approve this Consent  
22 Decree in the form presented, this agreement is voidable at the sole discretion of either party and  
23 the terms of the proposed Consent Decree may not be used as evidence in any litigation between  
24 the parties.

25 20. Effective Date: The effective date of this Consent Decree shall be the date upon  
26 which the Court has entered the Consent Decree on the docket.

1           21.    Authorization: The undersigned representatives of the Parties certify that they are  
2 fully authorized by the party they represent to enter into and execute the terms and conditions of  
3 the Consent Decree.  
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5 IT IS SO ORDERED on this \_\_\_\_\_ day of \_\_\_\_\_, 2024.  
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10 UNITED STATES DISTRICT JUDGE  
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1 THE UNDERSIGNED PARTY enters into this Partial Consent Decree in the matter of *Alianza*  
2 *Nacional de Campesinas, et al. v. United States Environmental Protection Agency, et al.*, Case  
3 No. 4:23-cv-09030-JST,

4 FOR PLAINTIFFS ALIANZA NACIONAL DE  
5 CAMPESINAS, *et al.*:

6 Date

7 \_\_\_\_\_  
8 SYLVIA SHIH-YAU WU (CA BAR # 273549)  
9 Center for Food Safety  
10 600 California Street, Suite 12-013  
11 San Francisco, CA 94108  
12 swu@centerforfoodsafety.org  
13 (415) 826-2270

14 THE UNDERSIGNED PARTY enters into this Partial Consent Decree in the matter of *Alianza*  
15 *Nacional de Campesinas, et al. v. United States Environmental Protection Agency, et al.*, Case  
16 No. 4:23-cv-09030-JST,

17 FOR DEFENDANTS UNITED STATES  
18 ENVIRONMENTAL PROTECTION AGENCY, *et al.*:

19 TODD KIM  
20 Assistant Attorney General  
21 U.S. Department of Justice  
22 Environmental and Natural Resources Division

23 Date

24 \_\_\_\_\_  
25 LUCY E. BROWN  
26 RACHEL D. MARTINEZ  
27 Attorneys  
28 Environmental Defense Section  
P.O. Box 7611  
Washington, D.C. 20044-7611

PARTIAL CONSENT DECREE  
CASE NO. 4:22-cv-09030-JST