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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

NATURAL RESOURCES DEFENSE
COUNCIL *et al.*,

Plaintiffs,

v.

CHRISTINE TODD WHITMAN, Administrator
of the United States Environmental Protection
Agency *et al.*,

Defendants.

AMERICAN FARM BUREAU FEDERATION
et al.,

and

PEOPLE FOR THE ETHICAL TREATMENT
OF ANIMALS *et al.*,

Intervenors.

No. C 99-03701 WHA

**ORDER APPROVING PROPOSED
CONSENT DECREE; DISMISSING
COUNT SIX OF COMPLAINT
BROUGHT BY NRDC *ET AL.*;
DISMISSING COMPLAINT BROUGHT
BY AFBF *ET AL.***

INTRODUCTION

Farm workers, environmentalists, and cancer-related groups brought this action against the Environmental Protection Agency, challenging EPA’s allegedly inadequate regulation of pesticides. Subsequently, organizations representing pesticide manufacturers, agricultural interests, and animal rights intervened as plaintiffs. EPA and the original plaintiffs have now proposed a settlement, the subject of this order. The proposed settlement has three components:

1 a consent decree binding EPA to a timetable for promulgating pesticide regulations, voluntary dismissal
2 of a petition for review now pending in the Ninth Circuit, and voluntary dismissal of one cause of
3 action herein, subject to a private proposed settlement agreement. The intervenor-plaintiffs object to
4 the settlement on the grounds that it will harm their interests. This order holds that the proposed
5 settlement is fair, equitable, reasonable, legal, and in the public interest. Accordingly, the proposed
6 consent decree is **APPROVED**, and count six of complaint herein brought by the Natural Resources
7 Defense Council *et al.* is **DISMISSED**. All the causes of action brought by plaintiffs-in-intervention
8 the American Farm Bureau Federation *et al.* are **DISMISSED** as moot. The complaint brought by
9 plaintiffs-in-intervention People for the Ethical Treatment of Animals *et al.* is all that remains of this
10 action.

11 STATEMENT

12 In 1996, Congress passed the Food Quality Protection Act.¹ FQPA amended the statutory
13 regimes by which EPA was (and is) tasked with regulating pesticides: the Federal Food, Drug, and
14 Cosmetic Act, 21 U.S.C. 301–394, and the Federal Insecticide, Fungicide and Rodenticide Act, 7
15 U.S.C. 136–136y. FFDCA required EPA to set allowable levels of pesticide residues in foods, called
16 tolerances. Under FIFRA, EPA licensed pesticides and could prohibit the use of a pesticide if it
17 would have an “unreasonable adverse effect on the environment.” FQPA altered FFDCA in four
18 ways significant to this litigation. First, it set a more stringent standard for pesticide exposure than
19 previously existed. Second, it set a series of deadlines by which EPA was required reassess the
20 tolerances and exemptions to tolerances for 9,728 pesticide uses: 33% by August 3, 1999, 66% by
21 August 3, 2002, and 100% by August 3, 2006. Third, it required EPA to coordinate reassessments
22 under FFDCA with a similar re-registration scheme under FIFRA. Fourth, it required EPA to
23 propose for public review by August 3, 1998, an “endocrine disruptor screening program” to study
24 whether any pesticides have an estrogenic effect on the human endocrine system and to implement the
25 program by August 3, 1999.

26 FQPA further required EPA to publish by August 3, 1997, a schedule for accomplishing
27 tolerance reassessments. 21 U.S.C. 346a(q)(3). While FQPA gave EPA unreviewable discretion in
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¹ Pub. L. No. 104-170, 110 Stat. 1489 (1996).

1 determining the sequence in which pesticides would be evaluated, it required EPA to adhere to the
2 schedule once it was set. *Ibid.* The schedule subsequently published by EPA required it to assess (i)
3 3,210 tolerances or exemptions by August 3, 1999, (ii) 6,420 tolerances or exemptions by August 3,
4 2002, and (iii) 9,728 tolerances or exemptions by August 3, 2006. 62 Fed. Reg. 42,019–22 (Aug. 4,
5 1997). The schedule divided pesticides into three groups. Group 1 was comprised of more than
6 5,000 pesticide uses that, according to EPA, “appear to pose the greatest risk to public health.” *Id.* at
7 42021. According to the schedule: “In general, tolerances and exemptions from Group 1 pesticides
8 will be subject to reassessment first.” *Ibid.*

9 **The Parties**

10 On August 3, 1999, plaintiffs the Natural Resources Defense Council, the Breast Cancer
11 Fund, CalPIRG Charitable Trust, Pesticide Watch Education Fund, Pesticide Action Network North
12 American Regional Center, San Francisco Bay Area Physicians for Social Responsibility, and United
13 Farm Workers of America, AFL-CIO (collectively “settling plaintiffs”), filed this action alleging that
14 EPA had failed to meet the tolerance-reassessment deadlines set by FQPA. Simultaneously, settling
15 plaintiffs filed a petition for review in the Ninth Circuit seeking to compel re-registration of pesticides
16 under FIFRA, which provided that certain decisions made under that act are reviewed directly by a
17 court of appeals. Settling plaintiffs subsequently amended their complaint to allege that (i) EPA had
18 failed to timely reassess the safety of organophosphates, (ii) had reassessed chemicals of lesser priority
19 first, contrary to the schedule EPA had published, (iii) had failed to reassess the proper number of
20 pesticides by August 3 as required by FQPA and EPA’s published schedule, and (iv) had failed to
21 meet the statutory deadline for implementing an endocrine-disruptor screening program. Settling
22 plaintiffs sought, *inter alia*, an injunction requiring EPA to comply with a court-ordered schedule for
23 the reassessment of organophosphates and other pesticides and for the establishment of an endocrine-
24 disruptor screening program.

25 The American Farm Bureau Federation, the American Crop Protection Association, and the
26 American Chemistry Council (collectively “objecting plaintiffs”) moved to intervene as plaintiffs on
27 November 1, 1999. Their motion was granted on December 8, 1999. In their complaint, objecting
28 plaintiffs alleged that EPA’s failure to timely reassess the use of pesticides created “great uncertainty

1 and hinder[ed] their ability to make the necessary planning and investments to ensure that their crop
2 protection products satisfy EPA’s reassessment standards” (AFBF Compl. ¶ 29). They sought a
3 “permanent injunction specifying that EPA must establish and adhere to a tolerance reassessment
4 schedule that satisfies all of the Agency’s responsibilities under FQPA relating to tolerance
5 reassessment” (*id.* ¶ 31). Substantially similar claims were made by AFBF in an action it had filed
6 against EPA in the District of Columbia on June 2, 1999. *See Am. Farm Bureau v. United States*
7 *Env’tl. Protection Agency*, 121 F. Supp. 2d 84 (D.D.C. 2000).² Objecting plaintiffs intervened in
8 the Ninth Circuit action as well.

9 On February 24, 2000, People for the Ethical Treatment of Animals, Physicians’ Committee
10 for Responsible Medicine, and the Doris Day Animal League (collectively “animal-rights plaintiffs”)
11 moved to intervene as plaintiffs. Their motion was granted on April 19, 2000. Their complaint was
12 entirely directed to the endocrine-disruptor screening program. According to animal-rights plaintiffs,
13 EPA had (i) failed to adopt a screening program as required by FQPA and (ii) had failed to
14 appropriately validate tests to be used in the endocrine-disruptor screening program, because it had
15 arbitrarily subjected tests that did not involve the use of laboratory animals to a more rigorous
16 validation process than was used for tests that involved animals. They sought a “permanent injunction
17 ordering the EPA to expeditiously validate and implement the non-animal in vitro assays and high
18 throughput screens necessary to comply with the FQPA” (PETA Compl. at 11).

19 **The Settlement**

20 Throughout the pendency of this litigation, settling plaintiffs and EPA were engaged in
21 settlement discussions through the Ninth Circuit’s mediation program. As a result, briefing in the Ninth
22 Circuit case was stayed. On January 12, 2001, EPA and settling plaintiffs finalized a draft of a
23 proposed settlement and provided it to the intervening parties for their comments. The proposed
24 settlement had three components. The first was that EPA would be bound by a consent decree setting
25 a schedule for making regulatory determinations under FFDCA and FIFRA. The second was that
26 settling plaintiffs would dismiss their cause of action regarding the endocrine-disruptor screening
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28 ² It is unclear whether the parties in the District of Columbia case were exactly the same as the
objecting plaintiffs herein.

1 program and their petition for review in the Ninth Circuit. And the third was that EPA would enter
2 into a private settlement agreement that it would make its best efforts to implement an endocrine-
3 disruptor screening program that had been proposed by an advisory committee formed by EPA,
4 EDSTAC (Endocrine Disruptor Screening and Testing Advisory Committee). The intervenors were
5 told that the settlement would be filed on January 19, but that they could continue to submit comments
6 that would be considered during the approval process (Weinstein Decl., dated Feb. 16, Exh. 2, at
7 2–3). By January 19, the intervenors had only made general comments about the proposed consent
8 decree, but had given more specific comments regarding the proposed private non-decree settlement
9 agreement regarding the endocrine-disruptor screening program. These comments, the settling parties
10 state, were incorporated into the proposed private settlement agreement (Olson Decl. ¶ 14; Weinstein
11 Decl., dated Feb. 16, Exh. 2). On January 19, settling plaintiffs and EPA filed the proposed consent
12 decree and the proposed private settlement agreement herein.

13 Objecting plaintiffs then filed an amended complaint on February 16 and then their first
14 amended complaint on February 20, which alleges that: (i) the Court lacks jurisdiction over the
15 portions of the proposed consent decree related to FIFRA; (ii) the proposed consent decree violates
16 FFDCA and FIFRA because it precludes EPA from considering relevant information; and (iii) the
17 proposed consent decree is arbitrary and capricious in violation of the Administrative Procedure Act,
18 5 U.S.C. 553 et seq.³

19 On March 13, objecting plaintiffs submitted comments on the proposed consent decree to the
20 settling parties. According to the settling parties, these comments resulted in significant changes to the
21 proposed consent decree (Olson Decl. ¶ 18). Animal-rights plaintiffs submitted comments on March
22 15, which were considered as well (*id.* ¶ 20). On March 19, Christine Todd Whitman, the newly-
23 appointed head of EPA, issued a directive to the agency. It read (Joint Notice of Filing, dated Mar.
24 21, 2001, Exh. A, at 1):

25 EPA staff has met with the Department of Agriculture, industry,
26 agricultural, and animal rights interveners in the NRDC v. Whitman
litigation, NRDC, and others to discuss the best way of implementing

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28 ³ The first amended complaint also alleges that the consent decree is rulemaking in violation of the
procedural requirements of the APA. Objecting plaintiffs, however, have withdrawn this argument (AFBF Final
Br. 19 n.24).

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the Agency’s obligations under the Consent Decree. This Directive is in response to a number of concerns raised at those meetings. The Agency also negotiated modifications to the Consent Decree to address some of these concerns. It is my goal for the Agency to conduct preregistration and reassessment activities in an open and transparent manner, with ample opportunities for public participation, and to make all regulatory decisions based upon principles of sound science. It is my belief that the Consent Decree is consistent with these goals, and I want to assure that the Consent Decree be implemented with these goals in mind. To that end, I am hereby directing the Office of Prevention, Pesticides, and Toxic Substances to do all the following . . .

The directive set forth fifteen separate procedures for EPA to follow in implementing the proposed consent decree as modified after discussions with the parties. The procedures were designed to allow public participation in the scientific determinations for which the proposed consent decree set deadlines: for example, holding a public meeting where interested parties could comment on EPA’s analysis of relative-potency factors, soliciting public comment on “common mechanism” determinations, and publishing toxicity studies being relied on for preliminary risk assessments (*id.* at 2–3). On March 22, settling plaintiffs and EPA submitted a revised proposed consent decree, almost identical to the one they now seek to have approved.

By order dated April 13, 2001, EPA was required to publish the terms of the proposed consent decree and its reasons for entering into it on its website and to allow public comment on the terms. In light of these comments, the issues were rebriefed. The hearing date on approval of the settlement was postponed, however. In the interim, the case was re-assigned to the undersigned.

On August 31, 2001, the settling parties submitted an amended proposed consent decree, since EPA had completed certain activities required under previously-proposed consent decree. Additionally, the amended proposed consent decree extended two deadlines to allow EPA time to consider recently-received studies. It is this amended proposed consent decree that the parties now seek to have approved.

The Eleventh-Hour Supplemental Declaration

Shortly before the September 6 hearing on the approval of the proposed consent decree, objecting plaintiffs submitted the supplemental declaration of three declarants: Chris Wilkinson, Micheal Genevan, and Robert Sielken. The declaration responded to a relative-potency study published by EPA on July 31, 2001. As will be explained, this study was a preliminary step in

1 conducting one of the scientific determinations required by the proposed consent decree, the
2 preliminary cumulative-risk assessment for organophosphates. According to the declaration, the study
3 revealed that there were fundamental flaws in EPA’s methodology, which would render compliance
4 with the deadline in the consent decree, December 1, 2001, impossible. At the hearing on September
5 6, it was stated that EPA’s methodology for the relative-potency study was currently under review by
6 the Scientific Advisory Panel (“SAP”), an independent peer-review group that oversees EPA’s
7 determinations under FIFRA. At the hearing, objecting plaintiffs argued that the SAP would not
8 endorse EPA’s methodology. Since review and decision by SAP was imminent, the Court declined to
9 rule on the proposed consent decree so that it could consider the results of the SAP review and allow
10 further briefing. SAP’s report was submitted by EPA on September 14. As EPA predicted at the
11 hearing, the report revealed no serious flaws in EPA’s methodology.

12 **Statutory Framework**

13 **1. The Federal Food, Drug, and Cosmetics Act**

14 As stated, the FFDCA required the EPA to establish “tolerances” for every pesticide. A
15 tolerance was the maximum allowable level of pesticide residue in a given food. 21 U.S.C.
16 346a(b)(1). In other words, a pesticide used on different foods had a separate tolerance for each
17 food. On its own initiative or in response to petitions from the public, EPA was allowed to establish an
18 exemption from a tolerance, if the statutory safety standard had been met. 21 U.S.C. 346a(c)(1)–(2).
19 Foods containing pesticide residues for which no tolerance had been set or containing a pesticide-
20 residue level exceeding the tolerance established by EPA could not be sold. 21 U.S.C. 331(a),
21 342(a)(2)(B), 346a(a). When EPA set a final tolerance, the tolerance was published, and anyone
22 could file an objection to the tolerance and request an administrative hearing on the merits of the
23 objection, which was subject to judicial review. 21 U.S.C. 346a(g)(2).

24 Before 1996, EPA was required to set tolerances that were “safe for use, to the extent
25 necessary to protect the public health” in consideration of a number of factors, and to allow
26 exemptions “when such a tolerance is not necessary to protect the public health.” 21 U.S.C. 346a(b),
27 (d) (1995). FQPA changed this standard by defining “safe” as “a reasonable certainty that no harm
28 will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary

1 exposures and all other exposures for which there is reliable information.” 21 U.S.C. 346(b)(2)(A)(ii).
2 Overall, FQPA required EPA to consider the following factors that EPA was not previously required
3 to assess: the cumulative effects of substances sharing a “common mechanism of toxicity,” the effect of
4 “aggregate exposures” (exposures through water and residential uses as opposed to merely food), and
5 the possible increased susceptibility of infants and children. 21 U.S.C. 346a(b)(2).

6 In addition, because the FQPA amendments implemented a more stringent standard, FQPA
7 required EPA “as expeditiously as practicable” to “review” 9,728 pesticide tolerances and exemptions
8 that were in existence at the time the amendments were enacted to determine whether they satisfied the
9 new standards. 21 U.S.C. 346a(q). It stated: “In conducting a review of a tolerance or exemption,
10 the Administrator shall determine whether the tolerance or exemption meets the requirements of
11 subsections (b)(2) or (c)(2) of this section and shall, by the deadline for the review of the tolerance or
12 exemption, issue a regulation under subsection (d)(4) or (e)(1) of this section to modify or revoke the
13 tolerance or exemption if the tolerance or exemption does not meet such requirements.” *Ibid.* This
14 review process was known as reassessment.

15 As stated, FQPA provided the following schedule for the reassessment: (i) 33% within three
16 years of August 3, 1996, (ii) 66% within six years of August 3, 1996, and (iii) 100% within ten years
17 of August 3, 1996. 21 U.S.C. 346a(q)(1). EPA was required to give priority in the reassessment
18 process to those tolerances and exemptions that “appear to pose the greatest risk to public health.”
19 21 U.S.C. 346a(q)(2). It was also required to “the extent practicable and consistent with the review
20 deadlines” established by FQPA, to coordinate any revocation of a tolerance or exemption with “any
21 related necessary action under the Federal Insecticide, Fungicide, and Rodenticide Act.” 21 U.S.C.
22 346a(l)(1).

23 2. The Federal Insecticide, Fungicide, and Rodenticide Act

24 FIFRA prohibited the sale, distribution, or use of a pesticide not registered with EPA.
25 7 U.S.C. 136a(a). A pesticide could be registered if EPA determined that it would “not generally
26 cause unreasonable adverse effects in the environment.” 7 U.S.C. 136a(c)(5)(D). “Unreasonable
27 adverse effects in the environment” was defined to include “a human dietary risk from residues that
28 result from a use of a pesticide in or on any food inconsistent with the standard under Section 346a of

1 Title 21 [FFDCA].” 7 U.S.C. 136(bb). Under certain “emergency” conditions, EPA could exempt a
2 pesticide from the registration requirement. 7 U.S.C. 136p.

3 Under the 1988 amendments to FIFRA, EPA was required to re-register any pesticide first
4 registered before November 1, 1984, giving priority to those: (i) used in food, (ii) raising concerns
5 about contamination of potable groundwater or edible sea life, (iii) having outstanding data
6 requirements, and (iv) used on crops where worker exposure was most likely to occur. 7 U.S.C.
7 136a-1(c). The re-registration process occurred in phases, beginning with data gathering and
8 submission by interested parties. In one of the preliminary steps, EPA announced the eligibility of a
9 pesticide for re-registration in a RED (Reregistration Eligibility Decision). A RED contained
10 information such as the active ingredient, the toxicity data, the avenues of exposure, the list of data
11 considered by EPA, and EPA’s conclusion. If EPA determined that a pesticide was ineligible for re-
12 registration, it provided a draft notice of cancellation to SAP, the independent group of scientists that
13 reviewed EPA’s scientific decisions, and to the United States Department of Agriculture. 7 U.S.C.
14 136d(b). While there was no deadline for issuing a draft notice of cancellation, 60 days after issuing
15 one, EPA could issue a notice of cancellation. *Ibid.* At that time, any aggrieved person could request
16 an administrative hearing on whether the registration should be canceled. *Ibid.* Cancellation of the
17 registration was stayed during the pendency of the hearing. *Ibid.*

18 By the time FQPA was enacted in 1996, the FIFRA re-registration process was far from
19 completed. As part of the FQPA amendments to FIFRA, Congress explicitly required EPA to
20 coordinate pesticide registration under FIFRA with the reassessment of tolerances under FFDCA.
21 Specifically, FIFRA provided that no later than the time EPA re-registered a pesticide, EPA “shall
22 reassess each associated tolerance and exemption from the requirement for a tolerance issued under
23 Section 408 of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 346a); determine whether
24 such tolerance or exemption meets the requirements of that Act (21 U.S.C.A. 301 et seq.); [and]
25 determine whether additional tolerances or exemptions should be issued.” 7 U.S.C. 136a-
26 1(g)(2)(E)(i)–(iii).

27 **3. EPA’s Implementation of FIFRA and FFDCA**

1 EPA implemented pesticide re-registrations under FIFRA and tolerance reassessments under
2 FFDCAs through its Office of Pesticide Programs, which coordinated these efforts by issuing tolerance
3 reassessments under FFDCAs as part of a RED under FIFRA. In conjunction with EPA's duties
4 under FIFRA and FFDCAs, the Office of Pesticide Programs also developed several non-statutory
5 procedures to enhance stakeholder participation in the regulatory process. For example, for
6 organophosphates, one of the main groups of chemicals at issue in this action, the non-statutory
7 procedures and the determinations required by FIFRA and FFDCAs were all performed together in
8 sequence set forth below.

9 First, EPA would issue a preliminary risk assessment on an individual chemical. This study
10 included both the human health risk evaluation needed for tolerance reassessment under FFDCAs, and
11 the ecological risk assessment necessary for FIFRA re-registration. This was followed by public
12 comment, then a revised risk assessment, and then additional public comment. In some cases, EPA
13 then issued a RED, which contained all the risk management information, EPA's conclusions, and the
14 risk reduction measures necessary for re-registration. If, however, EPA determined that the pesticide
15 shared a common mechanism of toxicity with other pesticides and thus may have had a cumulative
16 toxic effect, it performed both a preliminary and final cumulative-risk assessment (with public comment
17 in between and after), before issuing a RED. Before a cumulative-risk assessment could be done,
18 individual risk assessments had to be performed for each related chemical. If EPA was unable to issue
19 a RED because a cumulative-risk assessment was necessary, it would publish an interim RED, which
20 was a complete RED, minus cumulative-risk-assessment data. In issuing a RED, EPA could issue a
21 final tolerance reassessment. If, however, EPA determined that a tolerance needed revocation or
22 adjustment, EPA issued a final rule, subject to notice and comment. If EPA found that a pesticide was
23 ineligible for re-registration, it issued a notice of intent to cancel the registration and then a notice of
24 cancellation. Only a final tolerance reassessment and notice of cancellation were subject to
25 administrative adjudication and judicial review.

26 **The Proposed Consent Decree**
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1 The proposed consent decree requires EPA to complete REDs for four pesticides and interim
2 REDs for six pesticides by specific deadlines.⁴ It sets December 1, 2001, as the deadline for EPA to
3 issue a preliminary risk assessment of the cumulative effects of 39 organophosphate pesticides
4 (Proposed Consent Decree ¶ 4). After 240 days of public comment, the final cumulative-risk
5 assessment will be due (*ibid.*). It sets deadlines for EPA to determine whether two groups of
6 pesticides share common mechanisms of toxicity (*id.* ¶ 10).⁵ It requires EPA to determine whether
7 three pesticides pose risks to workers that constitute unreasonable adverse effects on the environment,
8 and sets an eight-month deadline for EPA to send a notice of cancellation to SAP and USDA for
9 these pesticides, if EPA finds that this is required (*id.* ¶ 9).⁶ It also requires EPA to publish annual
10 reports providing updates on actions EPA has taken and plans to take pursuant to the proposed
11 consent decree (*id.* ¶ 11).

12 The proposed consent decree explicitly reserves settling plaintiffs’ right to challenge any final
13 agency action, and EPA’s defenses to such a challenge (*id.* ¶¶ 9b, 10, 15). It contains clauses that
14 provide that the consent decree does not require EPA to take any actions that are contrary to the law
15 (*id.* ¶¶ 18–19), provisions that allow non-compliance with certain deadlines if EPA determines that its
16 premises or methodology are “significantly flawed” (*id.* ¶ 5), and sections that allow EPA to delay
17 certain decisions if it is provided with new scientific information (*id.* ¶ 9d). Two provisions explicitly
18 preserve agency discretion (*id.* ¶¶ 17–18):

19 Except as provided herein, nothing in this Consent Decree shall be
20 construed to limit or modify the discretion accorded to the EPA by the
FFDCA, FIFRA, the APA, or general principles of administrative law.

21 Nothing in this Consent Decree shall bar EPA from acting on any
22 matters covered in this Consent Decree in a time frame earlier than

23
24 ⁴ The RED for propargite must be completed by September 30, 2001, and the REDs for benomyl,
25 endosulfan, and lindane by July 31, 2002 (Proposed Consent Decree ¶ 8). It sets the following dates for
26 completion of interim REDs: chlorpyrifos by September 30, 2001, atrazine by August 3, 2002, carbaryl by June
30, 2003, and diazinon by July 31, 2002 (*ibid.*). EPA must make its “best efforts” to complete interim REDs for
phosmet and azinphos-methyl by October 15, 2001, but must finish by October 30, 2001.

27 ⁵ It sets the following timetable: thiocarbamates and dithiocarbamates by December 31, 2001; and
28 triazenes by March 31, 2002. Originally, methyl carbamate and chloroacetanilides were included, but on July 10,
the EPA completed this determination for (EPA Notice, dated Aug. 21, 2001).

⁶ The pesticides are azinphos-methyl, chlorpyrifos, and diazinon.

1 required by this Consent Decree or to take additional actions not
2 specified herein if EPA determines such action are appropriate under
applicable law.

3 It also contains a dispute-resolution provision, which requires the parties to meet and confer before
4 seeking judicial enforcement (*id.* ¶ 24).

5 ANALYSIS

6 As a general matter, “a district court should enter a proposed consent judgment if the court
7 decides that it is fair, reasonable, and equitable and does not violate the law or public policy.” *Sierra*
8 *Club, Inc. v. Electronic Controls Design, Inc.*, 909 F.2d 1350, 1355 (9th Cir. 1990). As this
9 Court has recently noted, however, when a government agency is the target of a consent decree,
10 additional concerns about the decree’s effects on the agency’s long-term ability to exercise its
11 judgment and expertise are raised. *See Center for Biological Diversity v. Bureau of Land*
12 *Management*, No. C 00-00927 WHA, 2001 WL 777088, at *4–5 (N.D. Cal. March 20, 2001). In
13 such circumstances, a court must examine how long a proposed consent decree would tie the agency’s
14 hands in future matters.

15 Agency Discretion

16 This order finds that the proposed consent decree does not unduly tie the hands of the agency.
17 It does not dictate any substantive results, or otherwise prevent EPA from exercising its scientific
18 judgment. The decree has safety valves that would allow EPA to avoid deadlines if EPA determines
19 that it is required to consider new data or that its methodology is flawed. Specifically, it states, for
20 instance, that EPA shall be excused from the deadlines regarding the risk assessment for
21 organophosphates if EPA finds that “(1) the premises underlying EPA’s risk assessment of
22 Organophosphate Pesticides are significantly flawed or (2) the methodology for conducting the risk
23 assessment is significantly flawed” (Proposed Consent Decree ¶ 5). Moreover, it contains two
24 express provisions preserving EPA’s discretion regarding everything but the deadlines in the proposed
25 consent decree.

26 The proposed consent decree further upholds all avenues of public notice and comment and
27 EPA’s ability to respond to public concerns. It provides that the proposed consent decree does not
28 authorize “any action in contravention of the FFDCA, FIFRA, the APA, or any other law or

1 regulation, either substantive or procedural” (*id.* ¶ 19). And it states, “Nothing in this Consent Decree
2 alters or affects the standards for judicial review of final EPA action, or creates jurisdiction that would
3 otherwise not exist to review EPA action” (*id.* ¶ 15). Since REDs are a preliminary step in final
4 rulemaking, after a final rule has been issued, any affected person or entity can bring an administrative
5 challenge to the final rule, at which time implementation of the rule would be stayed. The consent
6 decree sets no deadlines for the promulgation of any final rule, thus allowing EPA to consider all
7 information required by law.

8 Finally, the proposed consent decree has a short duration. All but two activities required by
9 the proposed consent decree must be completed by August 2002. The only dates outside that
10 window are the deadline for the interim RED for carbaryl (June 30, 2003) and the deadline for the
11 revised risk assessment for metam sodium (August 31, 2004). Both of these deadlines fall within the
12 tenure of the administration that has now proposed the decree. The decree, therefore, will not bind
13 future presidential administrations.

14 Because the proposed consent decree allows EPA to use its scientific judgment in combination
15 with public notice and comment in the way that Congress envisioned, and because it will not bind
16 future administrations, it does not unduly hamper agency discretion. Accordingly, this is not an
17 impediment to entry of the proposed consent decree.

18 Objecting plaintiffs and others argue that the proposed consent decree still should not be
19 approved, because the Court lacks both jurisdiction over the complaint and jurisdiction to provide the
20 relief contemplated by the proposed consent decree. Additionally, they maintain that the worker-
21 safety provisions of the proposed consent decree do not result from a meeting of the minds and that
22 the proposed consent decree will require EPA to violate the law. All of these contentions as well as
23 whether the proposed consent decree is fair, equitable, and reasonable, and whether it is within the
24 public interest are addressed below. The threshold issue of jurisdiction is first considered.

25 **Jurisdiction**

26 **1. Jurisdiction Over Complaint**

27 According to objecting plaintiffs, the Court cannot approve the proposed consent decree
28 because it lacks jurisdiction over the complaint (AFBF Br. 10–11). In the proceeding AFBF brought

1 against EPA in the District of Columbia, objecting plaintiffs point out, the court dismissed two causes
2 of action for lack of jurisdiction.⁷ *See Am. Farm Bureau*, 121 F. Supp. 2d at 97–100. The decision
3 to dismiss the two claims was entirely based on standing. In that case, AFBF claimed that because
4 EPA had failed to abide by its published schedule for tolerance reassessments, AFBF: (i) had suffered
5 a procedural injury; (ii) was deprived of information necessary for investment, compliance, and
6 planning; and (iii) had suffered economic loss because pesticides that had not been reassessed were
7 unfairly labeled as “endocrine disruptors,” and were thus shunned by consumers, whereas if they had
8 been timely reassessed, they would have been shown to be safe. The court held that AFBF’s claimed
9 procedural injury was foreclosed by the section of FFDCA that provides: “the determination of
10 priorities for the review of tolerances and exemptions pursuant to this subsection is not a rulemaking
11 and shall not be subject to judicial review.” *Id.* at 97 (quoting 21 U.S.C. 346a(q)(3)). The court
12 rejected AFBF’s informational-injury argument, since FFDCA does not create a right to information.
13 *Id.* at 97–98. And the court found that in addition to failing to allege a particularized economic injury,
14 AFBF could not establish that such an injury was traceable to EPA’s conduct, as opposed to
15 Congress’s directive to reassess tolerances. *Id.* at 99–100.

16 The complaint at issue does not suffer from similar infirmities. Judicial review is proper under
17 21 U.S.C. 346a(q)(3) and under the APA. Specifically, the APA provides for judicial review to
18 “compel agency action unlawfully withheld or unreasonably delayed.” 5 U.S.C. 706(1). FFDCA
19 provides:

20 The determination of priorities for the review of tolerances and
21 exemptions pursuant to this subsection is not a rulemaking and shall
22 not be subject to judicial review, except that *failure to take final
action pursuant to the schedule established by this paragraph
shall be subject to judicial review.*

23 21 U.S.C. 346a(q)(3) (emphasis added). According to settling plaintiffs, EPA failed to abide by its
24 published schedule and failed to assess more one-third of the 9,700 tolerances in existence at the time
25 FQPA was passed.⁸ Taken as true, these facts provide an adequate basis for jurisdiction, since there
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27 ⁷ The court found jurisdiction over several of AFBF’s other claims.

28 ⁸ The complaint also makes three other allegations that were not contained in AFBF’s complaint in the
District of Columbia case. It is unnecessary to address them, however, as jurisdiction is apparent.

1 is a reviewable action — failure to take action pursuant to the schedule — that was unlawfully
2 withheld. Moreover, settling plaintiffs have alleged a cognizable injury: they allege that members of
3 their groups, such as farm workers, are regularly exposed to harmful pesticides, which is a concrete
4 and particularized injury (*e.g.*, NRDC Compl., Exh. F).

5 Objecting plaintiffs also argue that EPA has not conceded liability or that jurisdiction over the
6 settling plaintiffs’ complaint exists. No decision has held that an acknowledgment of liability is a
7 jurisdictional prerequisite for the entry of a consent decree. Resolving the merits of this dispute is
8 unnecessary, and indeed defeats the purpose of settlement. Rather, a court may enter a proposed
9 consent decree if the legal “claims alleged in the complaint are more than ‘wholly insubstantial and
10 frivolous.’” *Cronin v. Browner*, 898 F. Supp. 1052, 1057 (S.D.N.Y. 1995) (quoting *Bell v. Hood*,
11 327 U.S. 678, 776 (1946)). The settling plaintiffs’ complaint is more than adequate.

12 2. Jurisdiction to Provide Requested Relief

13 The thrust of objecting plaintiffs’ second jurisdictional argument is that the Court lacks
14 jurisdiction to approve the proposed consent decree, because the suit was brought under FFDCA, yet
15 the proposed consent decree requires EPA to issue REDs, which are part of the FIFRA regime.
16 Objecting plaintiffs contend that under FIFRA, the courts of appeals have exclusive jurisdiction over
17 “reregistration matters” (AFBF Final Br. 7). Since the consent decree sets schedules for achieving re-
18 registration under FIFRA, the Court is without jurisdiction to enter such an order, according to
19 objecting plaintiffs. Both sides agree that the following language from *Local Number 93*,
20 *International Association of Firefighters, AFL-CIO C.L.C. v. City of Cleveland*, 478 U.S. 501,
21 525 (1986), sets forth the applicable standard for the approval of a consent decree:

22 a consent decree must spring from and serve to resolve a dispute
23 within the court’s subject-matter jurisdiction. Furthermore, consistent
24 with this requirement, the consent decree must come within the general
25 scope of the case made by the pleadings, and must further the
26 objectives of the law upon which the complaint was based. However,
27 in addition to the law which forms the basis of the complaint, the
28 parties’ consent animates the legal force of a consent decree.
Therefore, a federal court is not necessarily barred from entering a
consent decree merely because the decree provides broader relief
than the court could have awarded after a trial.

Objecting plaintiffs focus on the first portion of the passage. They argues that *Firefighters* creates a
two-part test, under which a court may not approve a consent decree unless it (i) resolves a dispute

1 within the court’s subject-matter jurisdiction, and (ii) falls within the general scope of the case made by
2 the pleadings (AFBF Final Br. 6). According to objecting plaintiffs, “*Firefighters* requires that a
3 court have jurisdiction over all elements, not only of the complaint, but also of the consent decree
4 itself” (*id.* at 6–7). The settling parties, on the other hand, focus on the second half of this passage —
5 that a consent decree may encompass more relief than could have been obtained at trial.

6 Contrary to objecting plaintiffs’ view, a court may enter a consent decree that provides relief
7 beyond what a court could otherwise accord so long as some substantial part of it was within its
8 jurisdiction. In *Firefighters*, for instance, the Court upheld the approval of a consent decree under
9 Title VII, even though a provision of the statute may have rendered federal courts powerless to order
10 the relief provided for in the decree, had the case gone to trial. *Id.* at 526. Similarly, in *Sierra Club*,
11 909 F.2d 1350, the Ninth Circuit upheld a jurisdictional challenge to a consent judgment whereby the
12 defendant agreed to pay money to a private entity for violating the Clean Water Act, despite the
13 CWA’s provision that any fines for violation of the Act must be paid to the United States Treasury.
14 As discussed, there is jurisdiction over this action pursuant to the APA. The consent decree resolves
15 this dispute. That the parties wish to fold other relief into the consent decree does not run afoul of
16 *Firefighters*, because the consent decree resolves a dispute within this Court’s subject-matter
17 jurisdiction.

18 Objecting plaintiffs argue that neither *Sierra Club* nor *Firefighters* involved relief authorized in
19 a different statute. According to objecting plaintiffs, part of the relief contemplated by the proposed
20 consent decree — the deadlines for REDs — must be provided by the Ninth Circuit, because
21 Congress required that review of EPA decisions made under FIFRA is exclusively within the courts of
22 appeals. No decision, however, has endorsed objecting plaintiffs’ crabbed view. The rationale of
23 *Sierra Club* and *Firefighters* is that once a district court has jurisdiction over any substantial part of
24 the decree, the parties may consent to add more relief than could otherwise be obtained. As the
25 Court explained:

26 it is the agreement of the parties, rather than the force of the law upon
27 which the complaint was originally based, that creates the obligations
28 embodied in a consent decree. Consequently, whatever the limitations
Congress placed in § 706(g) on the power of federal courts to impose
obligations on employers or unions to remedy violations of Title VII,

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these simply do not apply when the obligations are created by a consent decree.

Firefighters, 478 U.S. at 522. Moreover, since REDs are not final, reviewable determinations, the proposed consent decree would not preclude the Ninth Circuit from reviewing any subsequent substantive determination made by EPA under FIFRA in contravention of congressional intent. In fact, Congress has required EPA to coordinate reassessments under FFDCA and re-registration under FIFRA, 7 U.S.C. 136a-1(g)(2)(E)(i)–(iii), and the proposed consent decree helps achieve this end. That the proposed consent decree requires EPA to issue REDs does not prevent its approval.

Objecting plaintiffs also argue that terms of the proposed consent decree do not fall within the general scope of the case made by the pleadings as required by *Firefighters*. According to objecting plaintiffs, the pleadings are directed to the timing of tolerance reassessments, which are not related to the REDs contemplated by the proposed consent decree (AFBF Final Br. 12). Objecting plaintiffs argue that under *Sansome Comm. v. Lynn*, 735 F.2d 1535 (3d Cir. 1984), a consent decree must be “directly responsive” to the complaint. *Sansome* involved a challenge to a consent decree regarding a redevelopment project. The court upheld the validity of the consent decree, reasoning: “Although the terms of the decree far exceeded the relief available under the NEPA and the NHA [National Housing Act], the decree was directly responsive to the Committee’s complaint under those statutes.” *Id.* at 1539. The Third Circuit’s analysis was no different than the Ninth Circuit’s approach in *Sierra Club*: both courts looked at the harm alleged in the complaint and whether the consent decree addressed that harm. The case made by the pleadings here is that the “agency has failed to carry out its statutory duties to reassess the safety of and take regulatory action on many chemicals that can have serious adverse effects on humans and cause substantial environmental harm” (NRDC First Amended Compl. ¶ 2). The complaint contains an extensive discussion of FIFRA (*id.* ¶¶ 15–20). The terms of the proposed consent decree, which establish time-frames for assessing the human and environmental harms posed by certain pesticides are directly responsive to the pleadings and “further the broad objectives upon which the complaint was based.” *Sierra Club*, 909 F.2d at 1355.

Worker-Safety Provisions

Objecting plaintiffs make the same jurisdictional argument regarding the provisions of the proposed consent decree that require EPA to consider worker safety that they make with regard to

1 the provisions setting deadlines for the issuance of REDs. For the reasons given above, that argument
2 is rejected. Additionally, objecting plaintiffs argue that these provisions are invalid because EPA and
3 settling plaintiffs disagree on the underlying law. They note that EPA claims that nothing in the consent
4 decree requires it “to consider worker risk in reassessing tolerances” (EPA Corrected Reply 16),
5 whereas settling plaintiffs claim “the FFDCA expressly mandates that EPA evaluate all routes of
6 exposure in reassessing tolerances” (NRDC Reply 14–15). According to objecting plaintiffs, there
7 was no “meeting of the minds” before settling plaintiffs and EPA struck the agreement, and therefore
8 the consent decree is not a contract between the parties (AFBF Final Br. 9). To the extent that EPA
9 and settling plaintiffs disagree about the law, this can be taken up if settling plaintiffs ever challenge any
10 of EPA’s substantive rules, which the proposed consent decree leaves them free to do. The consent
11 decree itself is directed to the timing, rather than the substance, of EPA’s decisions. The legal
12 disagreement between the settling parties is not fatal to entry of the proposed consent decree.

13 **Legality**

14 The consent decree is legal because it does not dictate any substantive result: it is directed
15 entirely to timing. As it explicitly states: “Nothing in this Consent Decree shall be interpreted as or
16 constitute a commitment or requirement that EPA obligate or pay funds in contravention of the Anti-
17 Deficiency Act, 31 U.S.C. 1341, or take any action in contravention of the FFDCA, FIFRA, the
18 APA, or any other law or regulation, either substantive or procedural” (Proposed Consent Decree ¶
19 19). Most significantly, nothing in the consent decree deprives any intervenor or objector of the right
20 to challenge any final action by EPA at the administrative or judicial level.

21 In response to EPA’s posting of the consent decree on its website, the Endosulfan Task Force
22 (an AFBF member) argued that “the Proposed Consent Decree only assures entities outside the EPA
23 an opportunity to address [EPA’s risk-benefits analysis] after the RED is published” (D-16657 at 9).⁹
24 In a similar vein, objecting plaintiffs argue that the proposed consent decree would force EPA to
25 ignore the Tolerance Reassessment Advisory Committee (“TRAC”). TRAC is a 52-member group
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⁹ The public comments were given docket numbers by EPA and provided to the Court in hard copy
and on CD-Rom. The number D-16657 corresponds to the numbers given by EPA.

1 co-chaired by EPA’s Deputy Administrator and the USDA’s Deputy Secretary. According to EPA, TRAC

2 was formed consisting of senior-level representatives of a wide variety
3 of stakeholders: environmental/public interest groups, farm worker
4 representatives, pesticide industry and trade associations, farmer and
5 grower organizations, food processors and distributors, State and
6 Federal agencies, pediatricians and public health groups. Moreover,
international observers from Canada and Mexico serve on the
Committee, and a high number of congressional staff are included as
meeting participants.

7 <http://www.epa.gov/oppfead1/trac/aug2000-summary.htm>. Even if both objecting plaintiffs and the
8 Endosulfan Task Force are correct, which is disputed (EPA Final Br. 14, 26) and contrary to the
9 Whitman directive, these contentions do not impugn the legality of the proposed consent decree,
10 because neither pre-RED public comment, nor input from TRAC are legally required under any
11 statute.

12 Because the proposed consent decree is within the Court’s jurisdiction and because its terms
13 are within the law, this order now turns to whether the proposed consent decree is fair, equitable, and
14 reasonable. Objecting plaintiffs and others argue that the settlement process was procedurally unfair,
15 and that the substantive terms are inequitable because they are unbalanced and unreasonable because
16 they will require hasty determinations grounded upon inaccurate data and methods. Publication of
17 studies based on these inaccuracies, they argue, will harm chemical suppliers and farmers.

18 **Fair, Equitable, and Reasonable**

19 **1. The Settlement Process**

20 Objecting plaintiffs argue that the negotiation process was improper and collusive. According
21 to objecting plaintiffs, they had been negotiating separately with EPA, and only learned about the
22 proposed settlement through a “surprise conference call” initiated by EPA (AFBF Br. 2). EPA,
23 objecting plaintiffs contend, gave objecting plaintiffs less than two weeks to comment on the decree
24 because “the timing had been dictated by the highest levels of the Agency — *i.e.*, outgoing Clinton
25 appointees” (*id.* at 3). A long-term agreement made by one administration that binds a subsequent
26 one raises legitimate policy concerns. *See Center for Biological Diversity*, 2001 WL 777088, at *5.

27 Whatever concerns may have been raised by the settlement process here have long been
28 dispelled. Due to the public-comment period imposed by the Court and the delays in this case, there
has been ample time for the public and the intervenors to respond to the terms of the proposed

1 consent decree. The Court further notes that the present administration does approve of the proposed
2 consent decree and that a Bush appointee, Robert Fabricant, General Counsel for EPA, has signed
3 the proposed consent decree on behalf of the government. The essence of objecting plaintiffs’
4 argument now seems to be that they themselves were not included in drafting the proposed settlement
5 of settling plaintiffs’ claims. While there is no legal requirement that the settling parties had to
6 incorporate, or even consider, any of objecting plaintiffs’ views, apparently they did. Nothing that
7 went on in the settlement process now prevents the approval of the proposed consent decree.

8 **2. Fairness**

9 The proposed consent decree appears to be a reasonable compromise, since there is an
10 adequate factual and legal basis, and because the relief embodied in the consent decree is considerably
11 less than what settling plaintiffs sought in their complaint and might have attained had this action gone to
12 trial. Without speculating on what the outcome of this litigation might have been, the Court finds that
13 settling plaintiffs have pursued plausible legal theories that have at least arguable factual support. In
14 their complaint, settling plaintiffs allege that by August 3, 1999, EPA had failed to reassess the safety
15 of all the tolerances for all organophosphates in violation of the schedule published by EPA (NRDC
16 First Amended Compl. ¶ 53). While EPA does not concede that it has failed to follow its schedule, it
17 does admit that organophosphates are “EPA’s top priority for reassessment” (EPA Final Br. 8). *See*
18 *also* 62 Fed. Reg. 42,021 (Aug. 4, 1997) (“it is EPA’s intent to conduct tolerance reassessments for
19 organophosphate pesticides in the first three years of the schedule”). Whether or not the statement in
20 the Federal Register was binding on EPA needs not be decided. Since the tolerance reassessments
21 for organophosphates have not been conducted, there is an adequate factual basis for entry of the
22 proposed consent decree as well.

23 The relief contemplated in the proposed consent decree is much less sweeping than the relief
24 requested by settling plaintiffs. The proposed consent decree merely sets deadlines for REDs and
25 interim REDs for a total of 11 pesticides. A RED is only a precursor to EPA issuing a final tolerance
26 reassessment. Had this action gone to trial, settling plaintiffs may have obtained much broader relief,
27 since they allege that EPA failed to meet the statutory deadlines for tolerance reassessment for around
28 1,000 pesticides (NRDC First Am. Compl. ¶¶ 59–66). Because the proposed consent decree

1 resolves a viable legal dispute in a fair manner, it is a reasonable disposition of settling plaintiffs'
2 complaint.

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5 **3. Timing Requirements**

6 Objecting plaintiffs and numerous objecting members of the public argue that the deadlines in
7 the proposed consent decree will lead to arbitrary decisions in violation of FFDCA, FIFRA, and the
8 APA. According to objecting plaintiffs, to meet the deadline for completing a preliminary cumulative
9 risk assessment for organophosphates, EPA will be unable to develop a valid methodology, “is likely
10 to overstate vastly the risk posed,” and will ignore the most accurate evidence on the toxicity of
11 organophosphates, data regarding the inhibition of cholinesterase in red blood cells (AFBF Final Br.
12 14–15).¹⁰ They further argue that the deadlines will preclude EPA from considering relevant data that
13 already exists or will soon exist: specifically, the USDA Supplemental Children’s Study, the OP
14 Market Basket Study, a study done by Dow Agrosiences, and human clinical data.

15 These challenges to EPA’s scientific judgment are unripe. During the rulemaking process,
16 objecting plaintiffs and every other member of the public will have the opportunity to provide any data
17 they wish EPA to evaluate. EPA in its discretion may consider such data or not. Whenever EPA
18 promulgates any final rule, the public can (and surely will) comment on the proposed rule and challenge
19 it at the administrative level and ultimately in court. Since no rules have been issued, it is wholly
20 unknown what studies EPA will eventually consider, what information will be available or considered
21 to be validated by EPA. Under the guise of opposing the entry of the proposed consent decree,
22 objecting plaintiffs are essentially seeking judicial review of non-final agency actions before they have
23 even occurred.

24 Objecting plaintiffs counter that publication of an erroneous study, even a preliminary one,
25 could damage their businesses. While this possibility exists, objecting plaintiffs fully participate in all
26 the preliminary proceedings, and, indeed maintain that peer review and public input are critical to

27 _____
28 ¹⁰ According to objecting plaintiffs, organophosphates are toxic because they inhibit cholinesterase in
the nervous system (Wilkinson Decl. at 5–6), and the most accurate method of assessing toxicity is by
measuring cholinesterase inhibition in red blood cells (*id.* at 15).

1 rational decisionmaking (*e.g.*, Opp. 13–14; Weinstein Decl., dated June 25, 2001, Exh. A, at 2; Exh.
2 B, Exh. G, at 12, Exh. J, at 2, Exh. K, at 3, Exh. N, at 2). EPA should not be penalized for making its
3 decisionmaking process more transparent and subjecting its policies to public comment before they
4 become final. Nor should these preliminary decisions be subject to judicial interference, as this would
5 contravene the Congressional mandate of APA and paralyze the regulatory process. Any RED issued
6 by EPA would have a stigmatic effect similar to the one feared and would not be subject to judicial
7 review. That these preliminary determinations are part of the proposed consent decree does not
8 change this.

9 EPA says it can meet the deadlines and do so professionally. Deference to the agency
10 Congress has designated to make these determinations is appropriate, especially at such a preliminary
11 stage, where objecting plaintiffs will retain all their statutory rights to notice and comment and judicial
12 review. EPA has submitted declarations indicating that it can consider the very studies objecting
13 plaintiffs deem critical. According to EPA, it can incorporate the “market basket study” into the
14 cumulative risk assessment for organophosphates (Mulkey Decl. ¶ 10) and it will incorporate the
15 children’s study into the final cumulative risk assessment (*id.* ¶ 11).¹¹ Based on the human clinical data
16 it has reviewed in the past, EPA’s policy is not to consider such studies (*id.* ¶ 20). Whether
17 substantial evidence will support this policy, or whether this will be EPA’s policy at the time of any
18 final rulemaking is entirely unknown.

19 Moreover, many of the objections made by objecting plaintiffs and others are that given the
20 data and methods that currently exist, issuing REDs will require EPA to use assumptions that will be
21 proven wrong by yet-to-be-completed studies. Studying the effects of pesticides is an ongoing
22 process. As will be discussed, the timing requirements of FQPA and the legislative history of both
23 FQPA and FIFRA demonstrate that Congress demanded prompt agency action under these laws. As
24 the court of appeals in the District of Columbia explained in rejecting EPA’s argument that it could
25 ignore current data because it wanted to consult its scientific advisory board first: “All scientific
26 conclusions are subject to some doubt; future, hypothetical findings always have the potential to

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28 ¹¹ EPA has stated that it would consider the results of the Dow study if it was submitted in July as
promised (Housenger Decl. ¶ 13). The Court is unaware of whether the study has been completed or submitted
to EPA.

1 resolve the doubt. . . . What is significant is Congress’s requirement that the action be taken on the
2 basis of the best available evidence *at the time* of the rulemaking. The word ‘available’ would be
3 senseless if construed to mean ‘expected to be available at some future date.’” *Chlorine Chemistry*
4 *Council v. Env’tl. Protection Agency*, 206 F.3d 1286, 1291 (D.C. Cir. 2000) (emphasis in original).
5 EPA’s decision to proceed based on the data currently available for some determinations appears
6 entirely reasonable, as FIFRA requires EPA to consider “all data submitted under this section
7 concerning an active ingredient” and “all other *available* data found by the Administrator to be
8 relevant.” 7 U.S.C. 136a-1(g)(1) (emphasis added). As already stated, the time to challenge whether
9 EPA is legally required to wait for yet-to-be-completed studies is after there has been a final agency
10 action.

11 Finally, the proposed consent decree postpones deadlines if EPA finds that its methodology or
12 data are flawed and allows for the consideration of new scientific information that could significantly
13 alter EPA’s assessment (Proposed Consent Decree ¶¶ 5, 9d). Whether EPA’s final rules will be
14 based on substantial evidence remains to be seen. The hypothetical scenarios posited by the objectors
15 cannot serve as a basis for refusing to approve the proposed consent decree.

16 **4. The Eleventh-Hour Supplemental Declaration**

17 This ruling was delayed because on August 20, objecting plaintiffs submitted the supplemental
18 declaration of Chris Wilkinson, Michael Ginevan, and Robert Sielken. These experts disagreed with
19 the relative-potency study published by EPA on July 31. This study was generated for calculating the
20 preliminary cumulative-risk assessment for organophosphates, which is required to be completed by
21 December 1, 2001, under the proposed consent decree. As stated, the relative-potency study was
22 reviewed by SAP at a meeting on September 5–6. Two of the three experts above attended the SAP
23 meeting and expressed their views, and AFBF submitted written materials. While objecting plaintiffs
24 argue that the scientific “flaws” in this study show that the proposed consent decree is unreasonable
25 and against the public interest, this declaration simply highlighted the deficiencies in objecting plaintiffs’
26 scientific arguments.

27 First, SAP disagreed with objecting plaintiffs’ evaluation of the relative-potency study.
28 Despite objecting plaintiffs’ prediction at the September 6 hearing that SAP would reject EPA’s

1 methodology, exactly the opposite has now occurred. Moreover, SAP rejected some of the specific
2 points raised by objecting plaintiffs' experts (*e.g.*, SAP Report at 3, rejecting arguments about "B"
3 factors). While SAP did not approve of every single aspect of EPA's methodology, it stated (SAP
4 Report at 2):

5 The EPA staff is to be congratulated on a skillful and creative
6 implementation of the basic aspects of the risk modeling approach
7 suggested at the September 2000 SAP meeting on this issue. The
8 Panel consensus was that the major statistical issues raised at the
9 previous meeting have been thoroughly addressed, although many of
the panelists recommended further exploration of modeling issues
arising out of additional mechanistic considerations especially those
that could lead to different expectations for low dose relationships
between dose and inhibition response.

10 This conclusion was entirely consistent with EPA's representations at the hearing — that SAP might
11 find specific flaws in its method that could be fixed, but that nothing would be found that prevented
12 compliance with the dates in the consent decree using sound science. Citing to comments made by
13 individual SAP members, which are not in the record, objecting plaintiffs argue that SAP's
14 endorsement was less ringing than the report states. The SAP consensus, however, was as stated
15 above. It is unsurprising that not every panel member shared the same view.

16 Second, SAP rejected objecting plaintiffs' argument that EPA would be unable to meet the
17 deadline for the cumulative-risk assessment in the proposed consent decree. Its report stated: "The
18 Panel concluded that it was possible that a draft risk assessment using this hazard and dose response
19 assessment could be completed by December, 2001, and strongly encouraged pursuit of this goal"
20 (SAP Report at 14). Thus, so far, the only peer review of EPA's work has vindicated its scientific
21 predictions in this litigation.

22 Third, this relative-potency study is a precursor to a preliminary cumulative-risk assessment,
23 which will be subject to public notice and comment before it becomes a final cumulative-risk
24 assessment. The final cumulative-risk assessment is a precursor to a RED, which is a precursor to a
25 final rule. As they did at the SAP meeting, objecting plaintiffs will have the opportunity to present their
26 views at all of these preliminary stages. Absent the consent decree, no avenue for judicial review of
27 such preliminary actions would exist, as it would allow those who wish to see the regulatory process
28 grind to a halt impose expense and delay on the government at every turn.

1 Fourth, SAP asked EPA to modify its methodology for the preliminary cumulative-risk
2 assessment. Further modifications will undoubtedly occur before the final cumulative-risk assessment.
3 There is simply no meaningful basis for determining whether the deadline will compel an arbitrary and
4 capricious rule, still years away.

5 Overall, the SAP report buttresses the points already made: that EPA's determination that it
6 can meet the deadlines in the proposed consent decree using good science is properly committed to
7 agency discretion, and that EPA has used its discretion in good faith. In sum, this order finds that the
8 proposed consent decree is a fair, equitable, and reasonable settlement of plausible legal claims.
9 EPA's scientific determination that it will be able to meet the deadlines in the proposed consent decree
10 using good science is due deference and more than adequately supported by the record. While this
11 weighs in favor of approval, the public interest must also be considered.

12 **Public Interest**

13 The consent decree is consonant with the congressional purpose behind FFDCa, FIFRA, and
14 FQPA. In setting the time frames under FFDCa and FIFRA, Congress intended to hasten the
15 reassessment of tolerances and the re-registration of pesticides. For instance, in passing the re-
16 registration requirements to FIFRA in 1988, the House Report noted:

17 The need for revisions to FIFRA embodied in S. 659 is well
18 documented. In recent years, reviews by this and other Committees
19 of Congress, the General Accounting Office, the National Academy of
20 Sciences, and others have reported on the exceedingly slow pace of
the EPA's progress in completing the reregistration of existing
pesticides according to current health and safety standards.

21 H.R. Rep. No. 939, at 28 (1988). It further noted:

22 GAO has concluded that at the present rate the reregistration task will
not be completed until the year 2024.

23 Concern about the inadequacy of data that support current pesticide
24 regulations fuels much of the controversy surrounding pesticide use.
Such concern, in turn, reinforces the desire by States and their political
25 subdivisions to assert greater control over pesticide use; leads to
demands for reform of EPA's special review and cancellation
26 procedures; prompts calls for more stringent safeguards for workers
exposed to pesticides; and generally spurs the effort to limit the use of
27 pesticides. Consequently, the polarized public debate that surrounds
pesticide use cannot be expected to subside until a successful
28 reregistration program restores confidence in the regulatory system
that governs pesticide approval and use.

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The current pace of reregistration thus explains why an accelerated reregistration program is the centerpiece of S. 659.

Id. at 29. In addition to according with Congressional purpose, the proposed consent decree has been approved by the current administration. And, as already discussed, the proposed consent decree preserves all forms of public notice and comment. All these factors, in addition to the deference owed to EPA’s determination as to how to marshal its resources favor finding that the proposed consent decree is within the public interest. This order still considers the comments submitted by members of the public.

Objections from the Public

After publishing the proposed consent decree on its website as ordered, in addition to receiving more than 2,000 comments in support of the proposed consent decree, EPA received around 700 objections. These objections came from individual farmers, state and local farm bureaus, politicians, and agricultural organizations. Several different individuals and entities, such as Joel Ball, County President of Huron County Farm Bureau, submitted a form letter, which stated the following objections: (i) EPA “chose to negotiate with only one of the several parties involved, ignoring farming interests;” (ii) the consent decree is “contradictory to the risk assessment process EPA developed under” TRAC and CARAT (the Committee to Advise on Reassessment and Transition), organizations which represent a broad array of stakeholders; (iii) the deadlines are “arbitrary and unrealistic,” forcing “hasty decisions in the absence of scientific evidence;” and (iv) the proposed consent decree could have a devastating economic impact (*e.g.*, D-16614). These points, and other key concerns raised by objectors are discussed below.

One of the most common public objections was that the proposed consent decree will force EPA to proceed prematurely, causing the EPA to use “default assumptions” far greater than the actual risks. As already discussed, if this occurs, the proper remedy will be to challenge the final agency action based on what evidence EPA chose to consider and what evidence was available. Such a challenge is not precluded by anything in the proposed consent decree.

Another concern frequently raised was that the proposed consent decree will force EPA to ignore input from TRAC and CARAT. Nothing in the proposed consent decree requires such a result, however. Moreover, as stated in the Whitman directive, in developing the proposed consent

1 decree and in obtaining internal approval of it, EPA tried to preserve all of its pre-existing procedures
2 for public comment on non-final agency actions. For instance, the first bullet point of the Whitman
3 directive stated: “The Office of Pesticide Programs (OPP) will use a variety of means to engage the
4 public in discussion on the best means of optimizing public participation in the conduct of the activities
5 covered by the Consent Decree. These will include using the Committee to Advise on Reassessment
6 and Transition (CARAT), either in full sessions or in workgroups, as well as other appropriate
7 methods” (Joint Notice of Filing, dated Mar. 21, 2001, Exh. A, at 1). Indeed, the Whitman directive
8 even established new extra-statutory procedures for allowing public input. For instance: “When
9 issuing each of the four ‘common mechanism’ determinations required under the Consent Decree,
10 EPA will solicit public comment on its determinations and will revise such determinations if the public
11 comments or other sources provide new data or present new approaches to the examination of the
12 existing data that warrant modification of the Agency’s initial determination” (*id.* at 3).

13 Other objectors have argued that entry of the proposed consent decree would inhibit other
14 extra-statutory procedures that EPA has developed. The Minor Crop Farmer Alliance, for instance,
15 went as far as arguing that entry of the proposed consent decree should be delayed until science-
16 policy statements from EPA are promulgated as formal rules (D-16630). Other objectors argued that
17 until some of the science-policy statements were finalized, the consent decree should not be entered
18 (*e.g.*, D-16634). No statutory duty to issue science-policy statements exists. Nor have these policies
19 ever been issued as formal rules. As stated, punishing EPA for voluntarily assure that its
20 decisionmaking process is transparent would create a perverse result.

21 Similarly, Uniroyal Chemical argues that the deadline for the RED for propargite, September
22 30, 2001, “fails to provide sufficient time for EPA to follow its own published process for developing
23 the RED” (D-16620 at 1). The Associate Director of the Special Review and Reregistration Division
24 in the Office of Pesticide Programs, however, states that EPA “should have sufficient time before the
25 September 30, 2001 deadline in the Consent Decree for issuance of the propargite RED to review
26 comments on the risk assessment, consult with stakeholders, and draft the RED” (Hounsenger Decl. ¶
27 12). Even if EPA were unable to follow all of its extra-statutory procedures for allowing public
28 comment on preliminary agency decisions, it seems to have made a reasonable choice in sacrificing

1 activities that are not statutorily required for ending a legal fight for allegedly failing to perform its
2 statutory duties.

3 For the reasons already given, the argument that the proposed consent decree was negotiated
4 in a collusive or unfair manner or in a way that ignored objecting plaintiffs’ interests is rejected. A draft
5 of the proposed consent decree was first distributed to the parties in this litigation in January. In April,
6 the final version of the proposed consent decree was published on EPA’s website. It is now
7 September. There has been ample time for public comment and ample time for consideration by the
8 current administration of EPA.

9 The last frequently-raised argument was that the proposed consent decree will have
10 devastating economic consequences. The proposed consent decree simply requires EPA to evaluate
11 certain chemicals: it does not dictate a particular consequences. Under FIFRA, EPA is required to
12 take into account “the economic, social, and environmental costs” in determining whether a pesticide
13 poses “unreasonable adverse effects on the environment.” 7 U.S.C. 136(bb). That a pesticide is
14 popular, however, does not exempt it from reassessment or re-registration. Under both FFDCa and
15 FIFRA, EPA is required to give priority to evaluating pesticides that appear to pose the greatest risk
16 to public health: nowhere is it required to assess the economic consequences of performing such re-
17 evaluations. 21 U.S.C. 346a(q)(2); 7 U.S.C. 136a-1(c)(1). The economic-consequences argument
18 seems to be a challenge to Congress’s determination that re-evaluation of the most potentially
19 dangerous pesticides had to occur quickly. To the extent EPA fails to properly account for the
20 economic benefits of a given pesticide in any final rule, judicial review will be available.

21 This order finds no merit in any of the other objections that have not been explicitly addressed.
22 For all the reasons given, the Court finds that the proposed consent decree is fair, reasonable, and
23 equitable, and within the public interest. There is no need for an evidentiary hearing as requested by
24 objecting plaintiffs. Accordingly, EPA and settling plaintiffs’ motion to enter the proposed consent
25 decree is **GRANTED**.

26 **The AFBF *et al.* Complaint**

27 The operative complaint brought by AFBF *et al.* alleges that: (i) the Court lacks jurisdiction
28 over the portions of the consent decree related to FIFRA; (ii) the consent decree violates FFDCa and

1 FIFRA because it precludes EPA from considering relevant information; and (iii) the consent decree is
2 arbitrary and capricious in violation of the APA. For the reasons given in this order, the consent
3 decree is entered, and those causes of action are **MOOTED**.

4 **Voluntary Dismissal of Count Six**

5 Pursuant to FRCP 41(a)(2), settling plaintiffs and EPA jointly move to dismiss without
6 prejudice count six of settling plaintiffs' first amended complaint. Count six alleges, *inter alia*, that
7 EPA has failed to meet the statutory deadline for implementation of an endocrine-disruptor screening
8 program mandated by FFDCA as amended by FQPA. Objecting plaintiffs do not oppose the
9 dismissal. Animal-rights plaintiffs, however, oppose on the ground that they will be prejudiced. Their
10 argument is not that the dismissal itself would be harmful, but rather that the proposed private
11 settlement agreement between EPA and settling plaintiffs would require EPA to embark on creating an
12 endocrine-disruptor screening program without validating its tests properly and without giving due
13 consideration to using tests that do not involve animals.

14 Under the terms of the proposed private agreement, EPA would make its "best efforts" to
15 implement the endocrine-disruptor screening program proposed in the final report of EPA's advisory
16 committee, EDSTAC (Compl. ¶ 17). Animal-rights plaintiffs argue that the problems with proposed
17 program are that it: (i) fails to mention specific statutory mandates regarding the validation and
18 approval of testing to be performed; (ii) grants EPA unfettered discretion to avoid using appropriately
19 validated tests; and (iii) "severely undercuts the possibility that new, non-animal screens and tests will
20 be used, thereby ensuring that massive numbers of animals

21
22 will suffer and die in the animal screens and tests that EPA has named" (PETA Final Opp. at 13, 25).

23 According to them (*id.* at 2):

24 Unless it is modified, the Settlement Agreement threatens to involve
25 the testing of as many as 87,000 substances using an estimated
26 600,000 to 1.2 million animals for every 1,000 chemicals tested, thus
27 constituting the largest animal testing program in history. EPA
28 continues to commit itself to a lower standard of validation for animal
tests than non-animal tests and has failed to agree to requisite
consultation and coordination with the Department of Health and
Human Services — which is under a duty to replace, reduce and
refine animal use in the program.

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For the foregoing reasons, the proposed consent decree is **APPROVED** and count six of NRDC *et al.*'s first amended complaint is **DISMISSED**. AFBF *et al.*'s complaint is **DISMISSED**. PETA *et al.*'s complaint is all that remains of this action. A separate case management order has set a schedule to bring this case to a final conclusion.

IT IS SO ORDERED.

Dated: September 24, 2001.

WILLIAM ALSUP
UNITED STATES DISTRICT JUDGE