SETTLEMENT AGREEMENT

Whereas, on August 3, 1999, plaintiffs Natural Resources Defense Council; The Breast Cancer Fund; CALPIRG Charitable Trust; Pesticide Watch Education Fund; Pesticide Action Network; San Francisco Bay Area Physicians for Social Responsibility; and United Farm Workers of America, AFL-CIO (collectively, " Plaintiffs") filed a complaint in the United States District Court for the Northern District of California (Case No. C-99-3701 CAL) against the United States Environmental Protection Agency ("EPA") and Carol Browner, the Administrator of EPA (collectively, "EPA") (Plaintiffs and EPA are "the Parties"), alleging, *inter alia*, that EPA has failed to meet a statutory deadline for implementation of the Estrogenic Substances Screening Program mandated in section 408(p) of the Federal Food, Drug, and Cosmetics Act ("FFDCA"), as amended by the Food Quality Protection Act, 21 U.S.C. § 346a(p);

Whereas, Plaintiffs sought, *inter alia*, to compel EPA to implement expeditiously an Endocrine Disruptor Screening Program that an EPA Federal Advisory Committee Act (FACA) Committee, the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), recommended to EPA, as a means of complying with section 408(p) of the FFDCA;

Whereas, Plaintiffs alleged that this Court has jurisdiction over this claim;

Whereas, on February 18, 2000, Plaintiffs filed a First Amended Complaint in the above-captioned case, in which Count Six contained allegations similar to those described above;

Whereas, to ensure compliance with the requirements of FFDCA section 408(p), 21 U.S.C. § 346a(p), EPA currently plans to continue to move forward in implementing the general tenets of the Endocrine Disruptor Screening Program (EDSP) as set forth in EPA's December 28, 1998, *Federal Register* Notice, Endocrine Disruptor Screening Program: Proposed Statement of Policy, 63 Fed. Reg. 71,542. The general tenets of this program include (1) a prioritization

process; (2) a Validation program; (3) Tier 1 screening; and (4) Tier 2 testing;

Whereas, as part of the program, EPA currently plans to address as part of the EDSP estrogenic, androgenic, and thyroid endpoints;

Whereas, EPA plans continually to consider the advisability of incorporating into the EDSP assessment of other endocrine endpoints as the science advances and assays become available;

Whereas, EPA currently intends to validate and include as part of the Program the in utero lactation assay; the following Tier 1 screens: ER/AR Binding, Steriodogenesis, Aromatase, Uterotrophic, Hershberger, Pubertal Female, Pubertal Male, Fish Reproduction Screen, Frog Thyroid; and the following Tier 2 tests: Mammalian Two-generation Assay, Avian, Fish, Amphibian, Invertebrate.

Whereas, EPA currently intends to follow an appropriate Validation program when validating the screens and tests that are part of the program;

Whereas, EPA currently intends to establish an Endocrine Methods Validation Committee (EMVC), in accordance with the Federal Advisory Committee Act, to provide independent advice and counsel to EPA on scientific issues associated with the conduct of studies necessary for validation of the assays that are part of the EDSP;

Whereas, EPA intends to appoint members to the EMVC with balanced representation from the following sectors: environmental/public interest organizations; public health organizations, including children's health representatives; animal welfare organizations; Federal Agencies; State, local and tribal governments; industry; academia; consumers; and the public;

Whereas, consistent with the goals of this program, EPA will endeavor to (1) reduce the

number of animals used in implementing the Endocrine Disruptor Screening Program (EDSP), (2) refine procedures to make animal tests used in the Program less painful or stressful, and (3) replace animals with non-animal systems, where scientifically appropriate;

Whereas, EPA continues to dispute Plaintiffs' allegations;

Whereas, the Parties wish to resolve Count Six of the First Amended Complaint;

Whereas, it is in the interest of the public, the Parties, and judicial economy to resolve this Count without further protracted litigation;

Whereas, the Parties have agreed to a settlement of Count Six without any admission or adjudication of any questions of fact or law,

Whereas, the Parties consider this settlement to be a just, fair, adequate and equitable resolution of the claims raised in Count Six;

NOW, THEREFORE, the Parties agree as follows:

I. GENERAL TERMS

1. This Settlement Agreement applies to, is binding upon, and inures to the benefit of the Parties, their successors, assigns, and designees.

II. DEFINITIONS

2. For purposes of paragraphs 3 through 9 of this agreement,

A. **Validation** is the process by which the relevance and reliability of a procedure are established for a specific purpose. Relevance describes the relationship of a test to the effect of interest and whether a test is meaningful and useful for a particular purpose. Reliability is a measure of the degree to which a test can be performed reproducibly within and among laboratories.

B. The **Endocrine Disruptor Priority-Setting Database** (EDPSD) is a database that EPA is constructing to assist it in prioritizing chemicals for Tier 1 screening–the first assay phase of the Endocrine Disruptor Screening Program. The EDPSD will allow EPA to group chemicals by common data elements (e.g., amount of releases to water, amount found in monitoring studies, reproductive effects information) so that EPA can compare chemicals on a consistent basis.

C. **Quantitative Structure Activity Relationship** (QSAR) is a mathematical equation that relates chemical structure to a physical or chemical property or biological activity of a chemical.

D. **Tier 1 Screens** are short term in vitro or in vivo assays to determine whether a chemical substance or mixture may interact with the endocrine system.

E. **Tier 2 Tests** are longer term assays designed to determine whether a chemical substance or mixture may cause endocrine-mediated effects and to identify, characterize , and quantify those effects.

F. The **Mammalian Two-generation Assay** is a test involving the mating and reproduction of two generations of offspring. The purpose of the test is to determine the effects of a chemical substance or mixture on mammalian fertility, development, and reproduction.

G. **Validation Status Report** means a report that contains very short, succinct statements as to (i) the dates validating laboratories started validation work on an assay; (ii) the dates EPA received data from the validating laboratories and whether EPA found the data acceptable; (iii) if EPA determined the data from any validating lab to be unacceptable, the

reasons for that determination and the steps EPA has taken to resolve the issue; (iv) an estimation of when validation will be complete; and (v) reasons for any delay in not meeting deadlines in paragraph 7.

III. ENDOCRINE DISRUPTOR SCREENING PROGRAM

3. EPA will use best efforts to complete development of the architecture of the Endocrine Disruptor Priority Setting Database by July 31, 2001. EPA will use best efforts to complete and validate the Quantitative Structure-Activity Relationship (QSAR) portion of the EDPSD by December 31, 2001. EPA will use best effort to ensure that the EDPSD will be operational by May 31, 2002. If at any time EPA anticipates that it will be unable to make the EDPSD operational by May 31, 2002, or if the EDPSD is not fully operational by May 31, 2002, it will notify the Plaintiffs and provide them semi-annual reports of its progress toward making the EDPSD operational. These reports will describe the reasons for the delay and provide an estimate of when the EDPSD will be operational.

4. EPA agrees to review any results or data that it receives from Japan related to its High Throughput Prescreening (HTPS) effort. EPA will use best efforts to determine within one year from receipt of such results or data whether to incorporate them into the EDPSD. EPA will not incorporate, inter alia, results that are not scientifically valid or not otherwise appropriate for inclusion into the EDPSD.

5. EPA will use best efforts to publish and solicit public comment on an initial list of chemicals for screening no later than December 31, 2002. If at any time EPA anticipates that it will be unable to publish such a list by December 31, 2002, or if it fails to publish such a list by December 31, 2002, it will notify the Plaintiffs and provide them with semi-annual reports of its

progress toward publishing such a list. These reports will describe the reasons for the delay and provide an estimate of when EPA will publish such a list.

6. EPA currently intends to validate and include as part of the EDSP the following Tier 1 screens: ER/AR Binding, Steriodogenesis, Aromatase, Uterotrophic, Hershberger, Pubertal Female, Pubertal Male, Fish Reproduction Screen, Frog Thyroid; and the following Tier 2 tests: Mammalian Two-generation Assay, Avian, Fish, Amphibian, Invertebrate. EPA also intends to validate and include as part of the program the in utero/lactation assay. Nothing in this settlement agreement shall be construed as limiting or modifying EPA's discretion to add to, subtract from, vary from, or modify the screens or tests that it includes in the EDSP.

7. EPA will use best efforts to complete Validation of all of the Tier 1 screens except the Frog Thyroid assay no later than December 31, 2003. EPA will use best efforts to complete validation of the Frog Thyroid assay. EPA will determine whether to include the Frog Thyroid assay as part of Tier 1 by December 31, 2002. If the Frog Thyroid assay proves not to be valid and/or EPA decides not to include it in the EDSP, EPA will use best efforts to identify in a timely manner another assay that will cover the thyroid endpoint that it was intended to cover, including but not limited to assays already included in Tier 1. EPA will use best efforts to complete validation of the in utero lactation assay no later than December 31, 2003. EPA will use best efforts to complete Validation of the Tier 2 Mammalian Two-generation Assay no later than December 31, 2004. EPA will use best efforts to complete Validation of certain other Tier 2 tests listed in, and subject to the second sentence of, paragraph 6 no later than December 31, 2005. If at any time EPA anticipates that it will be unable to complete Validation by any of these dates, or if it fails to complete Validation by these dates, it will notify Plaintiffs and provide them

with semi-annual Validation Status Reports of its progress toward completing Validation.

8. EPA will use best efforts to start requiring testing, using appropriate regulatory mechanisms, for certain Tier 1 screens listed in, and subject to the second sentence of, paragraph 6 no later than December 31, 2003. EPA will use best efforts to start requiring testing, using appropriate regulatory mechanisms, for certain Tier 2 tests listed in, and subject to the second sentence of, paragraph 6 no later than December 31, 2004. If at any time EPA anticipates that it will be unable to start requiring testing by any of these dates, or if it fails to require testing by any of these dates, it will notify Plaintiffs and provide them with semi-annual reports of its progress toward requiring such testing. These reports will describe the reasons for the delay and provide an estimate of when EPA will start requiring testing.

9. EPA agrees to keep the public informed of all results of priority setting, screening, and testing by publishing these results in a centralized place that is readily accessible to the general public.

IV. MODIFICATION

10. If a subsequent change in law alters or relieves EPA of its obligations concerning matters addressed in this Settlement Agreement, then the Settlement Agreement shall be amended to conform to such changes. Any dispute regarding invocation of this provision shall be resolved in accordance with the dispute resolution provision of Paragraph 12.

V. FORCE MAJEURE

11. The Parties recognize that performance under this Settlement Agreement is subject to fiscal and procurement laws and regulations of the United States which include, but are not limited to, the Anti-Deficiency Act, 31 U.S.C. § 1341, et seq. A force majeure event may

arise, due to circumstances outside the reasonable control of EPA, that could delay compliance with the obligations set forth in Paragraphs 3 through 9 of this Settlement Agreement. Such force majeure events include, but are not limited to, a government shutdown, such as occurred in 1995 and 1996, or catastrophic environmental events requiring immediate and/or time-consuming response by EPA. Emergency exemptions under section 18 of FIFRA shall not constitute a force majeure event for purposes of this Paragraph. Should a delay occur due to a force majeure event, any resulting failure to fulfill any obligations set forth herein shall not constitute a failure to comply with the terms of this Settlement Agreement, and any deadlines so affected shall be extended one day for each day of the delay. As soon as possible under such circumstances, EPA will provide Plaintiffs with notice invoking the relief provided for under this Paragraph, with an explanation of EPA's basis for invoking this relief. EPA shall also provide Plaintiffs with reasonable notice of the termination of the force majeure event upon which EPA invoked this relief. Any dispute regarding invocation of such relief shall be resolved in accordance with the dispute resolution provision of Paragraph 12 of this Settlement Agreement.

VI. DISPUTE RESOLUTION AND REMEDY FOR NONCOMPLIANCE

12. In the event of a disagreement between the parties concerning the interpretation or performance of any aspect of this Settlement Agreement, the dissatisfied party shall provide the other party with written notice of the dispute and a request for negotiations. The parties shall meet and confer in order to attempt to resolve the dispute within 30 days of the written notice, or such time thereafter as is mutually agreed. If the parties are unable to resolve the dispute within 60 days of such meeting, then Plaintiffs' may initiate an appropriate action at law. EPA does not waive or limit any defense relating to such litigation. Nothing in this Settlement Agreement

alters or affects the standards for, or availability of, judicial review of such an action. The Parties agree that contempt of court is not an available remedy under this Settlement Agreement.

13. Plaintiffs agree that they will not seek to enforce dates for implementation of the Endocrine Disruptor Screening Program that are earlier than those identified in Paragraphs 3, 4, 5, 7, and 8 of this Settlement Agreement either pursuant to FFDCA section 408(p) or any other authority.

VII. AGENCY DISCRETION

14. Except as expressly provided herein, nothing in this Settlement Agreement shall be construed to limit or modify the discretion accorded EPA by the FFDCA, FIFRA, the APA, or general principles of administrative law.

15. Nothing in this Settlement Agreement shall bar EPA from acting on any matters covered in this Settlement Agreement in a time frame earlier than required by this Settlement Agreement or to take additional actions not specified herein if EPA determines such actions are appropriate under applicable law.

VIII. COMPLIANCE WITH OTHER LAWS

16. Nothing in this Settlement Agreement shall be interpreted as or constitute a commitment or requirement that the United States obligate or pay funds in contravention of the Anti-Deficiency Act, 31 U.S.C. § 1341, or take any action in contravention of the FFDCA, the Administrative Procedure Act, or any other law or regulation, either substantive or procedural.

IX. USE OF THIS SETTLEMENT AGREEMENT

17. This Settlement Agreement shall not constitute an admission or evidence of any fact, wrongdoing, misconduct, or liability on the part of the United States, including without

limitation, EPA, its officers, or any other person affiliated with it.

18. This Settlement Agreement constitutes the entire agreement of the Parties concerning the terms and obligations discussed herein and subject to dispute in Count Six of the First Amended Complaint in this action. No other agreement shall govern the rights and/or obligations of the Plaintiffs and EPA with respect to the matters resolved by this Settlement Agreement, except in accordance with the terms stated herein.

X. TERMINATION

19. This Settlement Agreement terminates Count Six in Plaintiffs' action against EPA. Plaintiffs and Defendants agree jointly to move the Court to dismiss Count Six without prejudice.

XI. RELEASE

20. This Settlement Agreement constitutes a complete and final settlement (i.e., is in full satisfaction) of the claims asserted by Plaintiffs in Count Six, and all claims that Plaintiffs could have asserted with respect to the allegations of Count Six.

XII. ATTORNEYS' FEES AND COSTS

21. The fees and costs provided for in the Consent Decree related to the other Counts in the Plaintiffs' complaint in this action shall constitute full settlement of any claims for fees and costs associated with Count 6 in their complaint.

XIII. APPLICABLE LAW

22. This Settlement Agreement shall be governed by and construed under the laws of the United States.

XIV. MUTUAL DRAFTING

23. The Parties agree that this Settlement Agreement was jointly drafted by them. Accordingly, the Parties agree that any and all rules of construction to the effect that ambiguity is construed against the drafting Party shall be inapplicable in any dispute concerning the terms, meaning, or interpretation of this Settlement Agreement.

XV. THIRD-PARTY BENEFICIARIES

24. Nothing in this Settlement Agreement shall be construed to make any other person or entity not executing this Settlement Agreement a third-party beneficiary to this Settlement Agreement. The Parties consent to the form, substance and entry of this Settlement Agreement.

XVI. EFFECTIVE DATE

25. This Settlement Agreement shall become effective upon the date it has been signed by the Parties. The Parties hereby agree to notify the court expeditiously that they have resolved Count six in the first amended complaint, and Plaintiffs and Defendants agree jointly to expeditiously move the court to dismiss the count.

XVII. NOTICE AND CORRESPONDENCE

26. Any notice, including correspondence, required or made with respect to this Settlement Agreement, shall be in writing, effective upon receipt, and sent to the following persons, or to such other person or persons as any Party may subsequently identify (in accordance with this provision) to the other Parties:

For Plaintiffs:

Fred Altshuler
Altshuler, Berzon, Nussbaum, Rubin & Demain
177 Post Street
Suite 300
San Francisco, CA 94108

Erik Olson
Natural Resources Defense Council
1200 New York Avenue, N.W., Suite 400
Washington, DC 20005

For EPA:

Assistant General Counsel for Pesticides
Pesticides and Toxics Law Office
Office of General Counsel (2333A)
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Chief
Environmental Defense Section
Environment and Natural Resources Division
United States Department of Justice
P.O. Box 23986
Washington, D.C. 20026-3986
Attn: DJ # 1-05728

XVIII. COUNTERPARTS

27. This Settlement Agreement may be executed in any number of counterpart originals, each of which shall be deemed to constitute an original agreement, and all of which shall constitute one agreement. The execution of one counterpart by any Party shall have the same force and effect as if that Party had signed all other counterparts.

XIX. REPRESENTATIVE AUTHORITY

28. Each undersigned representative of the Parties to this Settlement Agreement certifies that he or she is fully authorized by the Party he or she represents to enter into and execute the terms and conditions of this Settlement Agreement, and to legally bind such Party to this Settlement Agreement. By the signatures below, the Parties consent to entry of this

Settlement Agreement.

FOR PLAINTIFFS:

Dated: 1/19/2001

Michael E. Wall for Erik D. Olson, with permission

Erik D. Olson
Adrianna Quintero
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Counsel for Plaintiffs
Natural Resources Defense Council
The Breast Cancer Fund
CALPIRG Charitable Trust
Pesticide Watch Education Fund
Pesticide Action Network
San Francisco Bay Area Physicians for Social Responsibility

Dated: 1/19/2001

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Natural Resources Defense Council

FOR EPA:

Dated: 1/19/01

Gary S. Guzy
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FOR EPA:

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LOIS J. SCHIFFER
Assistant Attorney General
Environment and Natural Resources Division

Dated: 1/19/01

By: [signature] For

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