CONSUMERS UNION
INSTITUTE FOR ENVIRONMENT AND AGRICULTURE

May 21, 2001

Public Information and Records Integrity Branch
Information Resources and Services Division
(7502C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

PROPOSED CONSENT DECREE AND SETTLEMENT AGREEMENT – IMPLEMENTATION OF FQPA

These comments are submitted on behalf of Consumers Union of United States, Inc.[1] and the Institute for Environment and Agriculture.[2]

We strongly support the terms and conditions contained in the proposed consent decree and settlement agreement entered into by the Environmental Protection Agency (EPA) to settle the lawsuit brought against it by the Natural Resources Defense Council (NRDC), the United Farm Workers, the AFL-CIO, the Breast Cancer Fund, Physicians for Social Responsibility (Bay Area) and several other environmental organizations. By settling the suit (*NRDC et al. vs. EPA*) in the manner laid out in the consent decree, EPA has agreed to long-overdue steps needed to comply with and implement the core provisions of the Food Quality Protection Act (FQPA). EPA is

[1] Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about goods, services, health, and personal finances and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* regularly carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions that affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

[2] The Institute for Environment and Agriculture is responsible for policy analysis of a variety of issues including farm price supports, water contamination, closed animal feeding operations, sustainable and organic farm practices, incorporating alternatives to pesticides and safer pesticides, the implications of and regulatory structure for biotechnology and other food and environmental policies. Such information is provided to the public, the press and policy makers.

well over a year behind schedule in implementing this landmark law that protects infants and children from high-risk exposure to pesticides, as documented in the February 11, 2001, Consumers Union report "A Report Card for the EPA: Successes and Failures in Implementing the FQPA" (accessible at http://www.ecologic-ipm.com/findings_CU.html).

The consent decree establishes a logical process that will help get FQPA implementation back on track. While it is not possible to make up lost time, the consent decree will clearly help compel the agency to remain focused on – and accomplish – the major science policy, data collection and risk assessment activities required to bring closure to its ongoing evaluations of Group One, high-risk pesticides, including of course the organophosphate (OP) and carbamate insecticides.

The arguments advanced by critics of the consent decree are misplaced. Their real concern is the impact of the statute. Defenders of the status quo typically cite the need for more time to collect additional data and produce more refined risk assessment policies, models, and calculations. An oft-encountered argument is that EPA should delay any action on the OPs, for example, until complete and reliable information is in hand on all routes of exposure and all possible risks across all OPs, so that no one insecticide is unfairly targeted simply because there are more complete data available on its uses and exposures. Anecdotal claims of crop losses and/or lack of alternatives are also commonly mentioned as further reasons for a "go-slow" approach. Specifically in the case of major OP uses triggering significant dietary exposures and risks, the number of proven, cost-effective alternatives is already sizable and growing more so every month.

The FQPA defines with considerable clarity the health-based standard that shall apply in deciding whether an existing tolerance must be lowered or revoked. Through its science policies and many technical advisory committee reviews and reports, the agency's basic approach in evaluating exposure and risk, as well as in defining acceptable risks, has been praised as sound and in step with the statute.

The consent decree properly requires EPA to reach closure in its decision-making process on many high-risk pesticides. It is well known by anyone following the implementation process, for example, that EPA estimates of cumulative exposure and risk to the OPs and carbamates exceeds by a wide margin the levels consistent with the FQPA's "reasonable certainty of no harm" standard. Does this mean EPA has complete information and ironclad methods to estimate all OP-based risks from all routes of exposure? Clearly the agency does not. But the agency does have more than ample information on both cumulative and individual pesticide dietary exposure levels and risks, in most cases stable over several years, to identify the pesticide crop uses accounting for the lion's share of risk.

In the case of the OPs, the consent decree will eventually compel EPA to issue a formal finding of excessive risk, a finding that will come as no surprise to individuals who have been studying the results reported in EPA's OP cumulative risk assessment documents issued over the last two years. This finding, coupled with the schedule for completion of reregistration eligibility decisions on high-risk OPs, will hopefully lead in 2002 to a set of risk mitigation measures on known high-risk uses not previously addressed by EPA tolerance reductions and/or use restrictions. We think there is strong and consistent evidence to guide EPA in targeting the

highest-risk uses and incrementally reducing uses and exposures. This will narrow the gap between today's clearly unacceptable levels of exposure and exposures that are closer to those meeting the FQPA safety standard; in the meantime, the agency can and no doubt will further refine its methods and seek more complete data on both exposures and toxicological potential.

The consent decree compels EPA to act to reduce risk when it has clear, convincing information documenting that risks posed by a given pesticide-crop use exceed the FQPA standard, notwithstanding the existence of some uncertainties regarding the full scope of exposures and risks. There will never be enough data to fully meet the demands of those who urge inaction in the name of sound science. In our judgment, there is already more than enough data on many high-risk pesticides for EPA to conclude that risks are excessive and that risk mitigation measures are essential. In the interests of sound public policy and sound science, we hope that EPA will begin imposing risk mitigation measures incrementally, targeting first the clearest and most unequivocal risk-drivers. We support the consent decree because it provides a framework and approach designed to achieve just this goal.

The Consent Decree Establishes a Framework to Get Implementation Back on Track

The FQPA requires EPA to ensure that pesticide tolerances present a "reasonable certainly of no harm" for infants and children. Under the law, EPA must determine whether a pesticide poses unique risks to pregnant or young animals and if so, the agency is to impose up to an additional 10-fold safety factor. The FQPA also requires EPA to study the effects of endocrine-disrupting pesticides, a task which will clearly take many years to complete given the complex scientific issues the agency must still confront.

The statute directs EPA to consider exposures from all possible routes – food, drinking water, residential, and others – and evaluate as a group pesticides acting by a common mechanism of action. Consumers Union has offered support for all these core provisions of the FQPA, and EPA plans for implementing them, in a series of presentations before EPA's Scientific Advisory Panel, as well as in comments on draft science policies. (All Consumers Union comments are available in the section "Comments" at: http://www.ecologic-ipm.com/findings_CU.html.)

Still, EPA has failed to live up to its legal obligations under the law to perform these important tasks and take the necessary actions to reduce tolerances when they sanction residue levels above what the statute allows. In addition, many deadlines have been missed.

Part I of Consumers Union's February 2001 "Report Card" analyzes EPA progress in nine major science policy areas. Ideally, all nine should have been completed and issued as final by early 1999, to allow EPA time to reach closure on the cumulative risk assessment of the OP insecticides by the August 1999 deadline so risk mitigation measures could be initiated and applicable to the year 2000 crop season. This first key milestone was missed for all Group One pesticides, with the exception of methyl parathion. As shown in Table 1.1 from Consumers Union's "Report Card" report, EPA took an average 1.8 years post-passage of the FQPA to issue the first draft of its nine science policy papers. The revised draft of the 10-X science policy

paper was not issued until 2.7 years after passage – a problem given that EPA was supposed to have its reassessment complete of over 220 Group One, risk-driver pesticides three years after passage, by August 1999. The final 10-X policy has yet to be issued, although the latest draft has been described by EPA as essentially complete.

Completing the OP Cumulative Risk Assessment

The consent decree properly focuses on bringing to closure the long-underway cumulative risk assessment (CRA) of the organophosphate insecticides, without doubt the chemical family posing the gravest acute and developmental risks to infants, children and pregnant women. This science policy paper moved through the EPA process even more slowly than the 10-X paper. It took about two years for the initial, incomplete draft to emerge, and 3.8 years for the revised draft to be issued. The policy is still not in "final" form, despite the fact it has been described in great detail for over two years and few details have changed.

It is important to note that the basic methodological steps required to carry out a CRA were outlined in the 1993 NAS report. A prototype OP-CRA on a set of about a dozen OPs found in major children's foods had been completed by the Environmental Working Group well before passage of the FQPA. It used basically the same approach as the EPA's OP-CRA, but EPA's current analysis is much more comprehensive and benefits from both more thorough, recent residue data and a number of valuable technical refinements.

At this stage, the basic features and core methods within an OP-CRA have been thoroughly discussed and debated through a series of commissioned scientific reviews and meetings of the Scientific Advisory Panel. At each stage, EPA's basic approach has been endorsed, while various opportunities for relaxing assumptions or incorporating novel sources of data have been discussed and/or recommended. Indeed, aspects of the EPA's proposed CRA methodology have been brought before the SAP seven times since its first review in March 1997.

Our numerous statements on EPA's evolving CRA methodology show that we agree with other analysts that much more work is needed to carry out a comprehensive, definitive OP-CRA. But we differ with critics of EPA's current CRA science policies, who argue that additional methodological refinements and more complete exposure data will dramatically lessen estimated risk levels. Quite to the contrary, we are reasonably certain that as more exposure data and refined methods are adopted, the agency's level of concern will likely rise because of the new exposures added to the estimates.

The need to bring the OP-CRA to closure was one of the compelling reasons that led NRDC to file the initial lawsuit. It remains equally compelling as justification for the consent decree, which calls upon the agency to issue a final OP-CRA by December 1, 2001. Given that the agency issued an essentially complete OP-CRA in the fall of 2000 for a Scientific Advisory Panel review, we think the December 2001 schedule is feasible and indeed an essential milestone.

Across all nine science policies, Consumers Union estimates that it will be at least 4 years between passage of the act and issuance of final, or near-final science policies. This propensity to be exceedingly thorough and seek multiple scientific reviews has, we believe, improved the content and clarity of the basic science policies now governing FQPA implementation. But we think EPA could have progressed more quickly and reached equally sound policies if it had focused on the core issues and not allowed consensus scientific judgments to be reopened for renewed debate, e.g., the seemingly endless consideration of whether OPs and carbamates work through the same mode of action. There was growing agreement in the scientific community before passage of the FQPA was that they surely do, as set forth in the 1993 National Academy of Sciences report *Pesticides in the Diets of Infants and Children.* Despite much additional dialogue and reconsideration of new and old data, this consensus judgment remains intact.

While we were not parties to the lawsuit, we believe that NRDC and its co-plaintiffs had ample grounds for filing this action and that settlement is much preferable to lengthy litigation, during which time little progress would be made in implementing the vital commitments contained in the FQPA.

As we understand it, EPA reached a settlement with NRDC and its co-plaintiffs on January 19, 2001. Under the terms of the proposed consent decree, EPA would agree to implement some of the key congressional mandates of both the FQPA and the 1988 amendments to the Federal Insecticide, Fungicide and Rodenticide Act. Our understanding is that the settlement would require EPA to:

- assess, by August 2002, the cumulative risks of all 39 organophosphate insecticides (often highly toxic chemicals that are the most widely used insecticides in the nation);
- determine on a specified timetable over the next year and a half whether the carbamate family of insecticides (often toxic, widely used insecticides); the triazine family of herbicides (weed killers that often get into drinking water, including atrazine, the No. 1 herbicide in the nation); and the "chlor-" family of herbicides (widely used weed killers that also are found in many drinking water supplies) act together as cumulative poisons. If EPA finds that they do have this cumulative effect, the FQPA requires the agency to ensure the public is protected from their cumulative risks;
- decide on a specified timetable how it will control or eliminate the risks of 11 highly hazardous pesticides: phosmet, azinphos-methyl, propargite, chlorpyrifos, atrazine, carbaryl, benomyl, endosulfan, lindane, diazinon and metam sodium (EPA already has taken action on some of the risks of a few of these pesticides, such as azinphos methyl and chlorpyrifos, but has not finalized how it will control their hazards);
- adopt on a specified timetable the necessary actions to protect farm workers from three of the most risky insecticides used on crops (azinphos methyl, chlorpyrifos and diazinon); and
- meet a specified timetable to initiate a program testing for the effects of pesticides and certain other chemicals on the body's hormone-controlled endocrine system.

We support these goals as laid out in the consent decree. It would do nothing more than require EPA to implement important provisions of the law – something it should obviously be doing anyway. Indeed, under the terms of the consent decree, EPA would be required to reassess fewer pesticide tolerances than the law requires of it. In addition, the proposed consent decree does not require that any final regulatory action be taken.

We are aware that agricultural interests are seeking to get EPA to renege on the promise it made in its good faith negotiations with NRDC to settle this action. However, we believe that EPA should not now buckle under to pressure from those who would undermine compliance with the FQPA. Undermining the terms of this consent decree would only serve to undermine the health of infants and children.

We urge EPA to stay the course, confirm the terms of the proposed consent decree, and fully implement the provisions of the FQPA.

Sincerely,

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