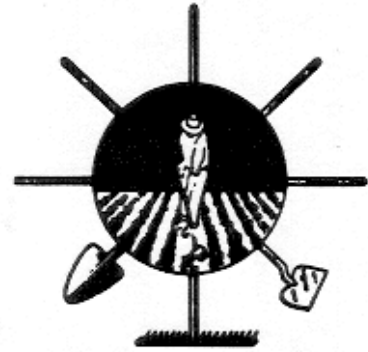


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December 11, 2005

U.S. Environmental Protection Agency
Public Information and Records Integrity Branch
Office of Pesticide Programs, 7502C,
1200 Pennsylvania Avenue, NW
Washington DC 20460
opp-docket@epa.gov

Re: Docket ID #: OPP-2003-0132.

Dear Sir or Madam:

These comments are submitted on behalf of the following groups and individuals:

The Farmworker Justice Fund Inc. is a national non-profit advocacy and education center for migrant and seasonal farmworkers, based in Washington D.C. Founded in 1981, FJF's mission is to empower migrant and seasonal farmworkers to improve their wages and working conditions, health status, access to justice, immigration status and ability to organize unions. For the past quarter century, FJF has advocated for a reduction in the use of toxic pesticides and an improvement in safety in the agricultural workplaces

Alaska Community Action on Toxics (ACAT), ACAT is a statewide non-profit public interest research and advocacy organization dedicated to protecting environmental health and achieving environmental justice. Our mission is: to assure justice by advocating for environmental and community health. We believe that everyone has the right to clean air, clean water, and toxic-free food. We work to stop the production, proliferation, and release of toxic chemicals that may harm human health or the environment.

Beyond Pesticides is a national non-profit membership organization, which serves as a national network committed to pesticide safety and the adoption of alternative pest management strategies to reduce or eliminate a dependency on toxic chemicals.

California Rural Legal Assistance Foundation is a statewide advocacy organization dedicated to assisting farmworkers and other low income rural residents in improving their living and working conditions.

California Safe Schools, a coalition of over 45 organizations, was established in 1998 by Robina Suwol, parents, students, environmentalists, physicians and concerned community members, after Robina's sons and other students were sprayed by a Los Angeles Unified gardener using hazardous materials. California Safe Schools is primarily responsible for California's Assembly Bill <http://www.leginfo.ca.gov/cgi-bin/postquery?bill_number=ab_405&sess=CUR&house=B&author=montanez>AB 405, a bill banning the use of experimental pesticides in California schools, recently signed by Governor Arnold Schwarzenegger.

The Heartland Center/Office is concerned with public policy reach, education of the communities in Northwest Indiana, especially through the Peace and Social Justice Commissions of the parishes of the Diocese, and community action. In addition, Fr. James M. Dixon, S.J. is the Diocesan coordinator with the Catholic Rural Life Conference

The Maryland Pesticide Network is a coalition of 25 health provider, health effected, onsumer, labor, environmental and religious organizations in Maryland concerned about the impact of pesticides on public health and the environment.

The Migrant Clinicians Network, based in Austin, TX, is a national non-profit, membership organization. It is the oldest and largest clinical network serving the mobile underserved. MCN works to improve the health of migrant and seasonal farmworkers and other underserved mobile populations. It addresses the unique health care needs and barriers for these populations through leadership, innovation, collaboration and support to health care providers.

The Missouri Organic Assoc. that promotes organic agriculture in our state.

The NJ chapter of national Clean Water Action is a non-profit, action-oriented organization with 70,000 individual members and 100 environmental, community, labor, religious and student member groups. NJEF works to protect the environment, public health, and economic wellbeing in our communities.

Organic Valley, based in La Farge, WI, is the largest farmer owned organic cooperative in the country. We produce and market a wide range of certified organic food products

Potomac Vegetable Farms is an ecoganic vegetable farm on the outskirts of Washington D.C. in Fairfax County. We were certified organic from 1990 until a couple of years ago when we decided the expanded documentation required by the National Organic Standards was excessive. We continue to be fully committed to organic methods and market our produce through our roadside stand on Leesburg Pike, four miles west of Tysons Corner; local growers-only farmers' markets, and our Community Supported Agriculture program.

Rochester Roots vehemently opposes these proposed regs. allowing pesticides to be tested on human subjects; farmworkers have been the human subjects for years and it has cost them dearly in illness and death. Consumers have also been the unwitting test subjects. We are teaching city children to grow organic food.

In addition, these comments are submitted by Debbie Davis, DWD Longhorns/Seco Valley Ranch, Hondo, TX; Tom FitzGerald, Director, Kentucky Resources Council Inc., Frankford, KY; Nancy Hirschfield, President, Informed Choices, Slidell, LA; Tony Tweedale, MS in Env. Studies, Secretary, Montana-Coalition for Health, Environmental & Economic Rights (CHEER), Missoula MT; and Winter Garden Sustainable Agricultural Coalition, Hondo, Texas

I. Primary Conclusions

- The EPA should not consider, for any purpose, studies involving the intentional, non-therapeutic dosing of human subjects with pesticides, whether conducted before or after the promulgation of this rule.
- The sole exception to this blanket prohibition should be to consider pesticide studies involving human subjects, conducted before the issuance of this rule, that would lead the EPA to set a lower No Observeable Adverse Effect Level, and therefore, afford greater protections to people. Previously conducted, small-scale studies, which find no effect should ever be accepted, because they are both unethical and scientifically deficient, (since they lack statistical power).
- The EPA's purported prohibition against conducting intentional dosing studies of pesticides involving pregnant women, fetuses, infants or children, is far too limited and may well result in the conduct of such studies.
- EPA's protections for children, especially abused and neglected children and prisoners, are also too limited.

Our detailed comments follow.

II. Detailed Comments

1. Testing Poisons on Human Subjects is Unethical: The intentional non-therapeutic testing of toxic pesticides on human subjects is inconsistent with applicable national and international ethical standards. Under the Nuremberg Code, adopted by the United States after the heinous Nazi experiments on concentration camp victims came to light, a study using human subjects is unethical unless, *inter alia*, it is expected to "yield fruitful results for the good of society, unprocurable by other methods or means of study." The Helsinki Declaration, which was adopted by the World Medical Association to regulate medical testing, requires, *inter alia*, that there be a "reasonable likelihood" that the test subjects would benefit from the study. (World Medical Association, Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects, <http://www.wma.net/e/policy/b3.htm>). The Federal Insecticide Fungicide and Rodenticide Act (FIFRA) prohibits the "use [of] any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the tests and of any physical and mental health consequences which are reasonably foreseeable there from, and (ii) freely volunteer to participate in the test." (FIFRA, 7 USC 136 *et seq.*). /the Common Rule, initially issued by the U.S. Department of Health and Human Services requires: (i) approval and oversight by an Independent Review Board (IRB) of human studies conducted or supported by a federal agency; and (ii) informed consent of the test subjects. 45 CFR Part 46; 40 CFR Part 26. It also establishes the principle that the "risks to subjects be reasonable in relation to anticipated benefits, if any, to subjects, and

the importance of the knowledge that may reasonably be expected." *Id.* Prior to the publication of the proposed regulation, the EPA convened a Joint Subcommittee of its Science Advisory Board (SAB) and the FIFRA Scientific Advisory Panel (SAP). In a Report entitled *Comments on the Use of Data from the Testing of Human Subjects* (SAB/SAP Report), the Joint SAB/SAP Subcommittee found, *inter alia*, that the intentional testing of pesticides on human subjects should not be conducted if data is available from other sources (e.g., animal studies) or if the resulting data will lack adequate statistical power and that such studies should never involve children, pregnant women or other vulnerable populations." (SAB/SAP Report at 3) Further, the SAB/SAP Report stated that the "Subcommittee, in general, would not support human experimentation primarily to determine a No Observable Adverse Effect Level." (SAB/SAP Report at 11)

1.

First, the toxicity information needed to regulate pesticides can be obtained from animal studies, computer models, or case studies of accidental poisonings. For this reason, no intentional dosing studies involving human subjects should be permitted. (*See* Nuremburg Code; SAB/SAP Report at 8.) Indeed, EPA has for decades made regulatory decisions, based primarily on animal studies without the need for human subject research. Moreover, judging from previously conducted human studies, the small number of test subjects involved (i.e., generally, 6-50 subjects) and their limited diversity (i.e., usually healthy young adults) makes it unlikely that that this kind of research would yield important information of sufficient statistical power to shed light on the risks to the entire US population, especially the most vulnerable, i.e., fetuses, infants, pregnant women, and people with compromised immune systems. (*See* Nuremburg Code; Common Rule; SAB/SAP Report at 8). In light of the availability of alternative methods to procure adequate information, it is unethical to put human health at risk to secure pesticide toxicity information. (*See id.*)

Second, the human subjects who bear the risk of suffering adverse health effects will not personally benefit from the results of the studies. While people in poverty (especially in the Third World) may be willing to risk their health for a few hundred dollars, this paltry financial gain does not meet the requirement for personal benefit established by national and international ethical standards. (*See* Helsinki Declaration).

Third, chemical companies cannot "fully inform" the test subjects of the short- and long-term health consequences of their participation in a toxicity study, because many of these effects are unknown. Studies to establish toxicity levels are conducted at the beginning of the risk assessment process before many of the health effects are established. Moreover, due to delays by pesticide registrants and the limited scope of studies they undertake, the full range of health effects associated with pesticides that have been on the market for decades is not known. For example, companies do not conduct studies to determine the health effects caused by exposure to their products in combination with other pesticides, other household chemicals, other medications, etc. Moreover, even though in 1996, the Congress directed EPA to require pesticide manufacturers to test pesticides for endocrine disruption (a likely effect of some products), the Agency has yet to establish a protocol for doing this kind of study. Without knowing the full range of risks facing a human test subject, the companies cannot provide the information test subjects would need to give fully informed consent. (*See* FIFRA; Common Rule).

Fourth, nowhere in the risk assessment process, does EPA make a determination as to whether a pesticide is actually needed, in light of the alternatives available. Nor is there any requirement in the proposed rule for EPA to determine whether the available information from animal data, models or incident data is sufficient. As such, there is no basis for an IRB to find that putting human subjects' health at risk is justified to obtain important information not otherwise procurable or that the information that would be obtained from a human study would benefit society as whole. As such, intentional dosing studies involving human subjects is unethical and should not be permitted under a final rule issued by EPA. Moreover, EPA should not consider any future studies, which are conducted. (*See* Nuremburg Code; Common Rule).

2. The Rule does Not Actually Prohibit Using Pregnant Women and Infants as Test Subjects: The EPA purports to ban the use of pregnant women, fetuses, infants or children as test subjects in intentional dosing studies (*see* 40 CFS sections 26.220, 26.420), but the rule contains limitations and exceptions which effectively gut that prohibition. (*See Id.* at 26.101(j), 26.221, 26.421 and 26.603). The rule only covers studies where the researcher or sponsoring company "intends" to submit the test results to EPA for decision making under the two federal pesticide laws, FIFRA or the Federal Food Drug and Cosmetic Act (FFDCA), (*See Id.* at 26.101(j)). As such, studies conducted for other regulatory bodies (e.g., California or the European Community) or for other purposes (e.g., regulating pesticide under the Clean Water Act or Clean Air Act) are outside the limitations of this proposed regulation. The EPA has also created an unnecessary burden for itself by hinging coverage under section 26.101(j) on the "intent" of the fonder or researcher, and the rebuttable presumption in favor of coverage will be of little assistance. Information about intent is largely in the control of those who conduct the research. Thus, they can easily create memoranda showing that they intend the research for a purpose other than submission to EPA for consideration under the pesticide statutes - and undoubtedly the research would have more than one purpose (e.g., submission to California and EPA) so the documented purpose would in fact be true.

Moreover, even studies that are conducted in violation of the rule (i.e., section 26.220 or 26.420) could still be relied on by EPA if the agency determines that they are scientifically sound and "crucial" for public health. (*See id.* at 26.221, 26.421, 26.603). Regrettably there is no definition of the term "crucial" to public health. Nor are any criteria provided for making this determination. Thus, this exception could be invoked whenever the agency believes that using human data would preserve a pesticide. For example, "crucial" to public health could mean simply that use of the pesticide would make a fruit available at a cheaper price, so that it is likely that more people would eat it. Such a flimsy benefit could hardly justify putting pregnant women, fetuses, infants or children at risk - especially since they are the most vulnerable to the toxic effects of pesticide exposure. The best incentive EPA can provide to inhibit companies from conducting studies on pregnant women, infants and children is to categorically state that it will not utilize such studies for any purpose.

3. Studies Conducted Prior to the Adoption of the Rule Will Be Accepted Even if they don't meet Current Ethical Standards: Several dozen studies using human subjects have been submitted by chemical companies to EPA for the purpose of lowering required safety precautions. Under the proposal, EPA will consider them as long as they were not

fundamentally unethical (i.e., conducted with the intent of causing serious harm to test subjects) and met the ethical standards existing at the time they were done. (*See id.* at 26.601, 26.602). However, since these studies do not meet current ethical or scientific standards, they should not be considered. These studies were conducted on very few subjects (i.e., 6 to 50 individuals), the consent forms often mischaracterized the test substance as a medicine, instead of a pesticide and the researchers claimed that the participants' symptoms were not due to the pesticide exposure. No previously conducted studies should be accepted unless they comply with current ethical and scientific standards. Where researchers obtained consent based on a mischaracterization of the test substance or without fully informing the participants of the possible health consequences, the research should be rejected on ethical grounds. Where pesticide studies were conducted with a handful of subjects, instead of thousands typically used in comparable studies of medication, the pesticide studies should be excluded because they lack the statistical power needed to provide valuable information for the diverse US population as a whole, and thus, lack scientific validity.

The only valid purpose for accepting studies which do not meet current ethical standards, is when such research would support a lowering of the No Observable Adverse Effect level (the basis upon which EPA regulates pesticides), otherwise require greater restrictions on use or supports a cancellation of the registration. No previously conducted small-scale human study, which finds "no effect" should ever be used, because these small studies could have missed an effect that was present.

If the EPA were to allow the use of previously conducted studies, it should make findings as to the ethical standards existing since the promulgation of the Nuremberg Code, so that it is not required to engage in a fact finding on a case-by-case basis, when such studies are submitted.

4. *Failure to Regulate Observational Studies:* Observational studies that encourage pesticide use with incentives remain unaffected by the proposed rule. Studies such as the highly controversial Children's Environmental Exposure Research Study (CHEERS), would not be outlawed or restricted by the proposed rule. Any study submitted for consideration by the EPA should, at the least, comply with the Common Rule. And use of young children as test subjects should be highly restricted and only permitted when there the need is great, the risks are small and the protections are in place to minimize harm. The failure to include these studies under the regulatory rubric now could lead to years of delay before any regulatory controls are imposed on this type of research.

5. *Failing to Protect Particularly Vulnerable Populations of Children and Prisoners:*

The proposal undermines the protections afforded by the Common Rule by allowing a waiver of informed consent for abused or neglected children. The informed consent of a parent or guardian should always be required. When a parent is adjudged to be abusive or neglectful, such an individual could be disqualified from providing consent. In such circumstances, however, a legal guardian would be appointed for the child. The legal guardian, who is required to act in the best interests of the child, should be given the opportunity to give or withhold consent.

Similarly, the EPA appears to undermine the protections to be afforded children participating in studies if they are conducted outside the United States (26.401(a)(2)). It is unethical to afford children outside the US any less protection than would be required for children inside the U>

It is possible that some of the provisions of Subpart D are intended to apply to studies conducted or supported by EPA that are not intentional dosing studies. If this is the case, those provisions should explicitly state the circumstances under which they apply. Otherwise the mixing of provisions that apply to intentional dosing studies – and those that do not – merely invites confusion and noncompliance with the rules.

Finally, the rule should categorically prohibit the use of prisoners in intentional dosing studies. By virtue of their incarceration, prisoners lack the liberty to “freely” participate in a study. Consent may be obtained by coercive or other inappropriate influences, or to gain some small privilege or curry favor with the jailers. Because a prisoner is by definition not free, his/her consent cannot be “freely” given.

Your consideration of our comments is much appreciated.

Sincerely,
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