*Office of the General Counsel*
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December 12, 2005

Public Information and Records Integrity Branch (PIRIB)(7502C)
Office of Pesticide Programs (OPP)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Attention: Docket ID Number OPP-2003-0132

Dear Sir or Madam,

On behalf of the United States Conference of Catholic Bishops ("Conference") we are submitting the following comments in response to the notice of proposed rulemaking (RIN 2070-AD57) regarding a ban on intentional dosing human testing for pesticides when the subjects are pregnant women or children that was published in the Federal Register on September 12, 2005. 70 Fed. Reg. 53838. The Catholic Church is one of the major providers of health care in the world and we are particularly concerned with how the testing of pesticides on humans and the laws and regulations governing it will affect human beings, especially the very young, the very old and those with disabilities. It is often the powerless and vulnerable in our society, including children, born and unborn, and low-income families who face the greatest risk from harmful exposures and unethical testing.

On September 10, 2003, the Conference submitted comments on research involving human subjects. We expressed concern about how the new regulations might affect the protection of humans. As expressed in 2003, we are very concerned about using humans for the direct testing of pesticides under any conditions, particularly when they will not receive any direct or immediate benefit, but in fact may be harmed.

In these comments we will first address certain topics for comment identified in the preamble to the proposed rules and then address certain parts of the proposed rules.

1. Part II, D of the preamble, p. 53841, notes that the focus of the proposed rules is on intentional dosing human studies for pesticides. While we agree that this is a serious issue that needs to be addressed, we urge the Agency to address issues involving human testing of all classes of environmental substances. Appropriate ethical standards for investigator conduct are needed whenever testing is done on humans that could potentially put their health or welfare at risk.

2. In response to the issues raised in Part IV, C, 1-4, p. 53847, we recommend that the Agency (i) extend the application of the Common Rule to all research with human subjects under any of its statutory authority, regardless of whether or not it is intended for submission to the Agency, (ii) apply the Common Rule to all research with human subjects and not limit it to research involving intentional exposure or research measuring a toxic effect, and (iii) extend the Common Rule to all research with human subjects that the Agency uses in its decision-making.

3. In Part VI, C, 2, p. 53850, we recommend that proposed section 26.420 be made broader to extend the ban on testing involving children to include any testing that poses a threat to the health or welfare of children. In any testing of children, protection of their health and welfare should be the paramount concern.

4. In the final rule we recommend two changes in proposed section 26.124(b)(5), p. 53863. First, add ", including children" at the end of the second sentence. The Human Studies Review Board should include experts who have experience in children's health. Second, we recommend that the words "and on request" be deleted from the last sentence. The Review Board should be able to make appropriate recommendations to the Agency with or without a request.

5. We agree with proposed section 26.220, p. 53864, as written, relating to the ban on research involving intentional dosing of any pregnant woman, fetus or newborn and recommend that it be retained in the final rule.

6. We recommend that the Agency not rely on any research involving the intentional dosing of any pregnant women, fetuses or newborns, and therefore recommend that the "except" clause in proposed section 26.221, p.53864, be deleted from the final rule.

7. In proposed section 26.401(a)(2), p. 53864, we recommend adding in the final rule, after the word "may," the following clause: "except for research involving the intentional dosing of pregnant women, fetuses or newborns,". The protections for pregnant women, fetuses and newborns should apply to research conducted outside of the United States.

8. In proposed section 26.401(b), p. 53864, we recommend deleting the "except" clause from the last sentence in the final rule. Research involving observations of public behavior of children should not be excepted regardless of whether the investigator does or does not participate in the activities being observed.

9. We agree with the definition of children in proposed section 26.402(a), p. 53864, and recommend that it be retained in the final rule.

10. In proposed section 26.421 we recommend that the "except" clause be deleted from the final rule. We believe that the Agency should not be allowed to rely on any research involving intentional dosing of any child.

11. In proposed section 26.603, p. 53866, we recommend deleting from subsection (a) in the final rule the clause "or that involves intentional exposure of a pregnant woman, fetus, newborn, or child". In addition we recommend adding in the final rule the following new subsection (d): "(d) This section shall not apply to research involving intentional exposure or dosing of a pregnant woman, fetus, newborn, or child." In order to afford the maximum amount of protection for the health and welfare of pregnant women, fetuses, newborns and children, we believe the Agency should not be allowed to rely on research involving their intentional exposure or dosing.

We urge the Agency to adopt a policy that truly reflects the highest standards of respect for the dignity of persons who might participate in human testing. The final rule should reflect a special concern for the interests of vulnerable populations, such as children from before birth through adolescence, pregnant women, the elderly and those with fragile health due to compromised respiratory functions or other conditions. In no case should developing humans (i.e., children in utero, infants, young children or adolescents) be deliberately exposed to toxic chemicals. It is important that vulnerable persons, including the poor, not be offered financial incentives to participate in studies that may harm their health.

We appreciate the opportunity to submit the above comments.

Sincerely,

John A. Liekweg
Associate General Counsel