EPA Proposes Strict Ethical Safeguards on Human Studies Research

On September 7, 2005, EPA proposed a rule that will establish stringent enforceable ethical safeguards governing the conduct of third-party intentional dosing research with human subjects. Among other new ethical protections, EPA proposes to prohibit all new third-party intentional dosing research on pesticides with children and pregnant women intended for submission to EPA, and announced a categorical ban that EPA will neither conduct nor support any intentional dosing studies that involve pregnant women or children.

This rule is intended to ensure that people who volunteer for third-party pesticide studies involving exposure to humans are treated ethically, with full disclosure as to potential risks. These regulations from EPA are designed to strongly discourage and prevent the conduct of human studies that do not meet the highest ethical and scientific standards. In addition, the protections in the proposed rule are consistent with the recommendations from the National Academy of Sciences, the nation's foremost scientific review body.

For any new, intentional dosing studies with pesticides, this proposal would require researchers to do the following: (1) comply with the requirements of the Common Rule (current ethical standards for research conducted or supported by the federal government); (2) submit detailed study protocols to EPA prior to initiation so that EPA can review to ensure the study meets the new ethical protections and is scientifically sound; and (3) once the study is conducted, provide detailed information to EPA describing how the study met the necessary ethical protections.

This rule would also put in place standards that EPA would follow in determining whether to rely on human studies. The agency is proposing to establish a Human Studies Review Board to review study protocols and selected available studies. The new protections would apply to pesticide intentional dosing studies conducted by EPA, those supported or sponsored by EPA, and those conducted by a pesticide manufacturer or other researchers.

This rule focuses largely on pesticide studies because such studies have elicited a strong expression of public concern, and because the risks they potentially present to people who volunteer to participate.

EPA welcomes public input, and the proposal includes a 90-day public comment period. For more information on the rulemaking, visit: http://www.epa.gov/oppfead1/guidance/human-test.htm

Funding Opportunity

* The Northeastern Integrated Pest Management (IPM) Center is pleased to announce the availability of funding through its IPM Partnership Grants Program for 2006 (FY 2005 federal funds). The Center is seeking applications for six project types:

1. IPM Working Groups
2. State Network Projects
3. IPM Working Group Priorities
4. Regional IPM Publications
5. Critical and Emerging Issues
6. IPM Tactics Surveys, Crop Profiles, and Pest Management Strategic Plans

Proposal must be received by the Northeastern IPM Center by 5:00 p.m. on Friday, December 16, 2005. See the complete RFA for full submission instructions. If you have questions or need paper copies of the RFA, please contact grants manager John Ayers, Co-director of the Northeastern IPM Center, Pennsylvania State University (phone 814-865-7776; fax: 814-863-8175; email jea@psu.edu).

A Request for Applications (RFA) is posted on the Center's website at http://northeastipm.org/abou_fund.cfm

Agricultural and Environmental News

- EPA is issuing its Reregistration Eligibility Decision (RED) for the widely used agricultural, pasture and rangeland, and residential lawn herbicide 2,4-D. With the risk mitigation measures specified in the Agency's RED document, 2,4-D is eligible for reregistration and can be used without posing risks of concern to human health or the environment. This risk management decision was developed with significant stakeholder and public input through the Agency’s public participation process for reregistration and tolerance assessment (US-EPA: News, August 12, 2005).

- Pesticide registration service fees for most pesticide applications and tolerance actions will rise 5% Oct. 1, while EPA’s decision timelines for many actions will decrease, as per the dictates of an EPA rule published last June (Pesticide and Toxic Chemical News: September 16, 2005; Volume 7, Issue 178).

- Four states filed suit against USDA’s Animal and Plant Health Inspection Service (APHIS) Sept. 15 for its failure to properly implement a rule to control against destructive insects entering the country through solid wood packaging materials (Pesticide and Toxic Chemical News: September 21, 2005; Volume 7, Issue 181).

- The U.S. Environmental Protection Agency has ordered a Los Angeles, Calif., business to stop selling and distributing two unregistered pesticides, "MoldWash" and "MoldWash Household," products that claim to control fungus and toxic molds (US-EPA News; September 20, 2005).

- On August 18, Monsanto announced that growers planted the Roundup® Ready Corn 2 System on more than 24 million acres in 2005. That represents nearly 30% of the 81.6 million acres of corn USDA estimates were planted in the U.S. this season. It also represents an increase of more than 40% over last year's Roundup® Ready Corn plantings. Their numbers offer a glimpse at how USDA's official biotech acreage estimates break down. According to the June acreage report, biotech hybrids were planted on 52% of corn acres this year. All herbicide resistant hybrids, which include but are not limited to Roundup® Ready hybrids, accounted for 17% of corn acres planted, while stacked-gene hybrids accounted for 9% of corn acres. Bt hybrids made up the difference. Monsanto says one factor driving the growth in Roundup® Ready corn plantings this year is the approval of Roundup® Ready Corn 2 (NK603) for food and feed ingredients in the European Union. That move opened
markets for US growers, and ended channeling requirements for grain with the NK603 trait. (Agriculture Online, 8/15/05, via chemically Speaking UFL).

The most economically important insect pests in potato production in West Virginia are Colorado potato beetle, potato leafhopper, aphids, and European corn borer. Other insect pests that invade potato plants and cause noticeable damage include wireworm and flea beetle.

October 5-7, 2005
Northeast Division APS Meeting, Geneva, NY
http://www.apsnet.org/members/div/northeastern/

November 6-9, 2005
ESA Annual Meeting, Fort Lauderdale, FL
http://www.entsoc.org/New_ESA/annual_meeting/index.htm

November 15-16, 2005
APS Soybean Rust Symposium, Nashville, TN
http://www.apsnet.org/online/sbr/

February 14-15, 2006,
NEPDN Regional Meeting, Tampa, FL.
Deadline for registration is December 1, 2005. Please contact Karen Snover-Clift (kls13@cornell.edu) for more information.