

US EPA ARCHIVE DOCUMENT



# Proposed Rulemaking to Amend EPA Rules For the Protection of Human Subjects of Research

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## *EPA's 2006 Rule: "Protections for Subjects in Human Research"*

- Promulgated in February 2006, to effectuate the mandate in the 2006 Appropriations Act
- Modeled on the Common Rule
- Prohibits reliance on research involving intentional exposure of children and pregnant and nursing women
- Requires review of protocols for proposed research by EPA and the HSRB
- ...and more!



## *Legal Challenge to EPA's 2006 Rule*

- Lawsuit filed against EPA in Spring 2006 by
  - Natural Resources Defense Council, Inc.
  - Pesticide Action Network of North America
  - Pineros y Campesinos Unidos del Noroeste
  - Physicians for Social Responsibility,
  - Farm Labor Organizing Committee of the AFL-CIO
  - Migrant Clinicians Network
- Sen. Barbara Boxer, Sen. Bill Nelson, Rep. Henry Waxman, and Rep. Hilda Solis filed as *amici curiae* in support of petitioners



## *Petitioners' Central Arguments*

- The scope of the rule was inconsistent with the requirements of the 2006 Appropriations Act
- The substance of the rule was inconsistent with:
  - The principles proposed in the 2004 NAS report
  - The principles of the Nuremberg Code



## *Litigation Chronology*

- Briefs and oral argument before U. S. Court of Appeals for the Second Circuit – Fall 2006 through January 2007
- Litigation stayed to permit settlement negotiations in April 2009
- Settlement negotiations April 2009 through June 2010
- Settlement agreement filed June 18, 2010



## *Settlement Agreement*

- Defines schedule for proposed and final amendments to the 2006 rule
- Attachment contains negotiated rule language to be proposed for public comment
- Negotiated amendments address petitioners' three core legal challenges



## *Response to Scope Challenge*

- Under the 2006 rule, subparts K and L apply to all third-party research relevant to EPA actions under FIFRA or FFDCA (regardless of the test substance)
- To address the scope challenge, EPA is proposing to broaden the applicability of subparts K and L to also cover research involving intentional exposure to a pesticide submitted to or considered by EPA under any other regulatory statute administered by EPA





## *Expected Effect of Proposed Scope Changes*

- Will close a perceived loophole
- EPA expects very little impact
- EPA has not, to date, seen a study outside of the scope of the 2006 rule that would be within scope of the proposed amendments
- Will not affect the mix of new pesticide human studies submitted for review
- May affect a few actions taken by other EPA offices relying on research on "pesticides"



## *Response to Challenge re NAS Recommendations*

- Incorporate NAS recommendations in:
  - Topics to consider in science reviews
  - Topics to consider in ethics reviews
  - Scope of HSRB reviews
  - Core considerations for scientific validity



## *Effect of Proposed Revisions re NAS Recommendations*

- Reassurance that EPA and HSRB reviews are rigorous
- Codification of current procedures in rule, with format revisions in review documents to highlight compliance
- No effect on review outcomes



## *Response to Challenge re Consistency with Nuremberg Code*

- Drop all references to consent by a legally authorized representative of a subject who cannot consent for himself
- Require EPA to consider:
  - Whether consent is fully informed and freely given
  - Whether proposed new research takes into account the results of previous animal testing
  - Whether proposed human testing is necessary



## *Effect of Proposed Revisions re Consistency with Nuremberg Code*

- None expected



## *Requirements of Settlement Agreement*

- Propose amendments to subparts K-Q to be “substantially consistent” with negotiated rule language attached to the settlement agreement
- Rulemaking schedule:
  - Proposed rule to be signed by 18 Jan 2011
  - Final rule to be signed by 18 Dec 2011 .