§ 26.1603 Operation of the Human Studies Review Board.

EPA shall establish and operate a Human Studies Review Board as follows:

(a) *Membership.* The Human Studies Review Board shall consist of members who are not employed by EPA, who meet the ethics and other requirements for special government employees, and who have expertise in fields appropriate for the scientific and ethical review of human research, including research ethics, biostatistics, and human toxicology.

(b) *Responsibilities.* The Human Studies Review Board shall comment on the scientific and ethical aspects of research proposals and reports of completed research with human subjects submitted by EPA for its review and, on request, advise EPA on ways to strengthen its programs for protection of human subjects of research.

Subpart Q—Ethical Standards for Assessing Whether To Rely on the Results of Human Research in EPA Actions

SOURCE: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.1701 To what does this subpart apply?

This subpart applies to EPA's decisions whether to rely in its actions taken under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*) or section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a) on scientifically valid and relevant data from research involving intentional exposure of human subjects.

§ 26.1702 Definitions.

The definitions in § 26.1102 and § 26.1202 shall apply to this subpart as well.

§ 26.1703 Prohibition of reliance on research involving intentional exposure of human subjects who are pregnant women (and therefore their fetuses), nursing women, or children.

Except as provided in § 26.1706, in actions within the scope of § 26.1701 EPA shall not rely on data from any research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

[71 FR 36175, June 23, 2006]

§ 26.1704 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults conducted before April 7, 2006.

Except as provided in § 26.1706, in actions within the scope of § 26.1701, EPA shall not rely on data from any research initiated before April 7, 2006, if there is clear and convincing evidence that the conduct of the research was fundamentally unethical (e.g., the research was intended to seriously harm participants or failed to obtain informed consent), or was significantly deficient relative to the ethical standards prevailing at the time the research was conducted. This prohibition is in addition to the prohibition in § 26.1703.

§ 26.1705 Prohibition of reliance on unethical human research with non-pregnant, non-nursing adults conducted after April 7, 2006.

Except as provided in § 26.1706, in actions within the scope of § 26.1701, EPA shall not rely on data from any research initiated after April 7, 2006, unless EPA has adequate information to determine that the research was conducted in substantial compliance with subparts A through L of this part, or if conducted in a foreign country, under procedures at least as protective as those in subparts A through L of this part. This prohibition is in addition to the prohibition in § 26.1703.

§ 26.1706 Criteria and procedure for decisions to protect public health by relying on otherwise unacceptable research.

This section establishes the exclusive criteria and procedure by which EPA may decide to rely on data from research that is not acceptable under the standards in §§ 26.1703 through 26.1705. EPA may rely on such data only if all the conditions in paragraphs (a) through (d) of this section are satisfied: