§ 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 nonpregnant, 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 nonpregnant, 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:

(a) EPA has obtained the views of the Human Studies Review Board concerning the proposal to rely on the otherwise unacceptable data,

(b) EPA has provided an opportunity for public comment on the proposal to rely on the otherwise unacceptable data,

(c) EPA has determined that relying on the data is crucial to a decision that would impose a more stringent regulatory restriction that would improve protection of public health, such as a limitation on the use of a pesticide, than could be justified without relying on the data, and

(d) EPA publishes a full explanation of its decision to rely on the otherwise unacceptable data, including a thorough discussion of the ethical deficiencies of the underlying research and the full rationale for finding that the standard in paragraph (c) of this section was met.

PART 27—PROGRAM FRAUD CIVIL REMEDIES

Sec.