

will include the preparation and implementation of specific procedures and processes relating to the programs and activities of the individual agency, as necessary.

(c) The Under Secretary, Natural Resources and Environment (NR&E), is responsible for ensuring that agency implementing procedures are consistent with CEQ's NEPA regulations and for coordinating NEPA compliance for the Department. The Under Secretary, NR&E, through the Agricultural Council on Environmental Quality, will develop the necessary processes to be used by the Office of the Secretary in reviewing, implementing, and planning its NEPA activities, determinations, and policies.

(d) In connection with the policies and requirements set forth in this part, all USDA agencies are responsible for compliance with Executive Order 12114, "Environmental Effects Abroad of Major Federal Actions." Compliance will include the preparation and implementation of specific procedures and processes relative to the programs and activities of the individual agencies, as necessary. Agencies shall consult with the Department of State; the Council on Environmental Quality; and the Under Secretary, NR&E, prior to placing procedures and processes in effect.

[48 FR 11403, Mar. 18, 1983, as amended at 60 FR 66481, Dec. 22, 1995]

§ 1b.3 Categorical exclusions.

(a) The following are categories of activities which have been determined not to have a significant individual or cumulative effect on the human environment and are excluded from the preparation of environmental assessment (EA's) or environmental impact statement (EIS's), unless individual agency procedures prescribed otherwise.

(1) Policy development, planning and implementation which relate to routine activities, such as personnel, organizational changes, or similar administrative functions;

(2) Activities which deal solely with the funding of programs, such as program budget proposals, disbursements, and transfer or reprogramming of funds;

(3) Inventories, research activities, and studies, such as resource inventories and routine data collection when such actions are clearly limited in context and intensity;

(4) Educational and informational programs and activities;

(5) Civil and criminal law enforcement and investigative activities;

(6) Activities which are advisory and consultative to other agencies and public and private entities, such as legal counselling and representation;

(7) Activities related to trade representation and market development activities abroad.

(b) Agencies will identify in their own procedures the activities which normally would not require an environmental assessment or environmental impact statement.

(c) Notwithstanding the exclusions listed in paragraphs (a) of this section and § 1b.4, or identified in agency procedures, agency heads may determine that circumstances dictate the need for preparation of an EA or EIS for a particular action. Agencies shall continue to scrutinize their activities to determine continued eligibility for categorical exclusion.

[48 FR 11403, Mar. 18, 1983, as amended at 60 FR 66481, Dec. 22, 1995]

§ 1b.4 Exclusion of agencies.

(a) The USDA agencies and agency units listed in paragraph (b) of this section conduct programs and activities that have been found to have no individual or cumulative effect on the human environment. The USDA agencies and agency units listed in paragraph (b) of this section are excluded from the requirements of preparing procedures to implement NEPA. Actions of USDA agencies and agency units listed in paragraph (b) of this section are categorically excluded from the preparation of an EA or EIS unless the agency head determines that an action may have a significant environmental effect.

(b)(1) Agricultural Marketing Service

(2) Economic Research Service

(3) Extension Service

(4) Federal Corp Insurance Corporation

(5) Food and Consumer Service

(6) Food Safety and Inspection Service

(7) Foreign Agricultural Service

- (8) Grain Inspection, Packers and Stockyards Administration
- (9) National Agricultural Library
- (10) National Agricultural Statistics Service
- (11) Office of the General Counsel
- (12) Office of the Inspector General

[60 FR 66481, Dec. 22, 1995]

PART 1c—PROTECTION OF HUMAN SUBJECTS

Sec.

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AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 300v–1(b).

SOURCE: 56 FR 28012, 28018, June 18, 1991, unless otherwise noted.

§ 1c.101 To what does this policy apply?

- (a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appro-

priate administrative action to make the policy applicable to such research. This includes research conducted by federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the federal government outside the United States.

(1) Research that is conducted or supported by a federal department or agency, whether or not it is regulated as defined in § 1c.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a federal department or agency but is subject to regulation as defined in § 1c.102(e) must be reviewed and approved, in compliance with § 1c.101, § 1c.102, and § 1c.107 through § 1c.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

(b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) Research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic,