the date of submission shall be deemed approved.

PART 1b—NATIONAL ENVIRONMENTAL POLICY ACT

Sec.

1b.1 Purpose.

1b.2 Policy.

1b.3 Categorical exclusions.

1b.4 Exclusion of agencies.

AUTHORITY: 5 U.S.C. 301; 42 U.S.C. 4321 *et seq.*; E.O. 11514, 3 CFR, 1966–1970 Comp., p. 902, as amended by E.O. 11991, 3 CFR, 1978 Comp., p. 123; E.O. 12114, 3 CFR, 1980 Comp., p. 356; 40 CFR, 1507.3.

SOURCE: 48 FR 11403, Mar. 18, 1983, unless otherwise noted.

§1b.1 Purpose.

(a) This part supplements the regulations for implementation of the National Environmental Policy Act (NEPA), for which regulations were published by the Council on Environmental Quality (CEQ) in 40 CFR parts 1500 through 1508. This part incorporates and adopts those regulations.

(b) This part sets forth Departmental policy concerning NEPA, establishes categorical exclusions of actions carried out by the Department and its agencies, and sets forth those USDA agencies which are excluded from the requirement to prepare procedures implementing NEPA.

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

§1b.2 Policy.

(a) All policies and programs of the various USDA agencies shall be planned, developed, and implemented so as to achieve the goals and to follow the procedures declared by NEPA in order to assure responsible stewardship of the environment for present and future generations.

(b) Each USDA agency is responsible for compliance with this part, the regulations of CEQ, and NEPA. Compliance 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;

§ 1b.4

- (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) [Reserved]
- (4) Federal Corp Insurance Corporation
- (5) Food and Consumer Service
- (6) Food Safety and Inspection Serv-
 - (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, as amended at 76 FR 4802, Jan. 27, 2011]

PART 1c—PROTECTION OF HUMAN SUBJECTS

Sec.

1c.101 To what does this policy apply?

1c.102 Definitions for purposes of this pol-

icy.

1c.103 Assuring compliance with this policy-research conducted or supported by any Federal department or agency.

1c.104 Exempt research.

1c.105[Reserved]

1c.106[Reserved]

1c.107 IRB membership.

1c.108 IRB functions and operations. 1c.109 IRB review of research.

1c.110 Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

1c.111 Criteria for IRB approval of research.

1c.112 Review by institution.

1c.113 Suspension or termination of IRB approval of research.

1c.114 Cooperative research.

1c.115 IRB records.

1c.116 General requirements for informed consent.

1c.117 Documentation of informed consent.

1c.118 Applications and proposals lacking definite plans for involvement of human subjects.

1c.119 Research undertaken without the intention of involving human subjects.

1c.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal department or agency.

1c.121 [Reserved]

1c.122Use of Federal funds.

1c.123 Early termination of research support: Evaluation of applications and proposals.

1c.124 Conditions.

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

SOURCE: 83 FR 7269, Jan. 19, 2017 unless otherwise noted.

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

(a) Except as detailed in §1c.104, this policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research. This includes research