

designed to eliminate the potential for harmful environmental effects—internal or external—and to provide for lawful waste disposal.

(ii) Examples of this category of actions include:

(A) The development and/or production (including formulation, repackaging, movement, and distribution) of previously approved and/or licensed program materials, devices, reagents, and biologics;

(B) Research, testing, and development of animal repellents; and

(C) Development and production of sterile insects.

(3) *Licensing and permitting.* (i) Issuance of a license, permit, or authorization to ship for field testing previously unlicensed veterinary biological products;

(ii) Permitting, or acknowledgment of notifications for, confined field releases of genetically engineered organisms and products; and

(iii) Permitting of:

(A) Importation of nonindigenous species into containment facilities,

(B) Interstate movement of nonindigenous species between containment facilities, or

(C) Releases into a State's environment of pure cultures of organisms that are either native or are established introductions.

(4) *Rehabilitation of facilities.* Rehabilitation of existing laboratories and other APHIS facilities, functional replacement of parts and equipment, and minor additions to such existing APHIS facilities.

(d) *Exceptions for categorically excluded actions.* Whenever the decision-maker determines that a categorically excluded action may have the potential to affect "significantly" the quality of the "human environment," as those terms are defined at 40 CFR 1508.27 and 1508.14, respectively, an environmental assessment or an environmental impact statement will be prepared. For example:

(1) When any routine measure, the incremental impact of which, when added to other past, present, and reasonably foreseeable future actions (regardless of what agency or person undertakes such actions), has the potential for significant environmental impact;

(2) When a previously licensed or approved biologic has been subsequently shown to be unsafe, or will be used at substantially higher dosage levels or for substantially different applications or circumstances than in the use for which the product was previously approved;

(3) When a previously unlicensed veterinary biological product to be shipped for field testing contains live microorganisms or will not be used exclusively for *in vitro* diagnostic testing; or

(4) When a confined field release of genetically engineered organisms or products involves new species or organisms or novel modifications that raise new issues.

[60 FR 6002, Feb. 1, 1995; 60 FR 13212, Mar. 10, 1995]

#### § 372.6 Early planning for applicants and non-APHIS entities.

Each prospective applicant who anticipates the need for approval of proposed activities classified as normally requiring environmental documentation is encouraged to contact, at the earliest opportunity, APHIS' program staff.

[60 FR 6002, Feb. 1, 1995; 60 FR 13212, Mar. 10, 1995]

#### § 372.7 Consultation.

Prospective applicants are encouraged to contact APHIS program officials to determine what types of environmental analyses or documentation, if any, need to be prepared. NEPA documents will incorporate, to the fullest extent possible, surveys and studies required by other environmental statutes, such as the Endangered Species Act.

[60 FR 6002, Feb. 1, 1995; 60 FR 13212, Mar. 10, 1995]

#### § 372.8 Major planning and decision points and public involvement.

(a) *Major planning and decisions points.* The NEPA process will be fully coordinated with APHIS planning in cooperation with program personnel. Specific decision points or milestones will be identified and communicated to