

(2) *Research and development activities.* (i) Activities that are carried out in laboratories, facilities, or other areas 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 decisionmaker 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, and 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.

#### § 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 opportunities, APHIS' program staff.

#### § 372.7 Consultation.

Prospective applicants are encouraged to contact APHIS programs 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.

#### § 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 the public and others in a notice of intent and in the context of the public scoping process.

(b) *Public involvement.* There will be an early and open process for determining the scope of issues to be addressed in the environmental impact statement process.

(1) A notice of intent to prepare an environmental impact statement will be published in the **Federal Register** as soon as it is determined that a proposed major Federal action has the potential to affect significantly the quality of the human environment. The notice may include a preliminary scope of environmental study. All public and other involvement in APHIS' environmental impact statement process, including the scoping process, commenting on draft documents, and participation in the preparation of any supplemental documents, will be pursuant to CEQ's implementing regulations.

(2) Opportunities for public involvement in the environmental

assessment process will be announced in the same fashion as the availability of environmental assessments and findings of no significant impact.

(3) Notification of the availability of environmental assessments and findings of no significant impact for proposed activities will be published in the **Federal Register**, unless it is determined that the effects of the action are primarily of regional or local concern. Where the effects of the action are primarily of regional or local concern, notice will normally be provided through publication in a local or area newspaper of general circulation and/or the procedures implementing Executive Order 12372, "Intergovernmental Review of Federal Programs."

(4) All environmental documents, comments received, and any underlying documents, including interagency correspondence where such correspondence transmits comments of Federal agencies on the environmental impact of proposals for which documents were prepared (except for privileged or confidential information (50 FR 38561)), will be made available to the public upon request. Materials to be made available will be provided without charge, to the extent practicable, or at a fee not more than the actual cost of reproducing copies required to be sent to other Federal agencies, including CEQ.

#### § 372.9 Processing and use of environmental documents.

(a) Environmental assessments will be forwarded immediately upon completion to the decisionmaker for a determination of whether the proposed action may have significant effects on the quality of the human environment, and for the execution, as appropriate, of a finding of no significant impact or a notice of intent to prepare an environmental impact statement.

(1) The availability of environmental assessments will be announced by publishing a notice consistent with the notification provisions of § 372.8.

(2) Comments, if any, will be transmitted, together with any analyses and recommendations, to the APHIS decisionmaker who may then take appropriate action.

(3) Changes to environmental assessments and findings of no significant impact that are prompted by comments, new information, or any other source, will normally be announced in the same manner as the notice of availability (except that all commenters will be mailed copies of changes directly) prior to implementing the proposed action or any alternative.