

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 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 inter-agency 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