Accordingly, 7 CFR part 301 is amended as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 147a, 150bb, 150dd, 150ee, 150ff, 161, 162, and 164–167; 7 CFR 2.22, 2.80, and 371.2(c).

§ 301.52 [Amended]

2. In § 301.52, paragraph (a) is amended by removing the words ''Missouri,'' and ''Tennessee,''.

3. Section 301.52–2a is amended as follows:

a. The entry for Arkansas is revised to read as set forth below.

b. The entry for Missouri and all of the material pertaining to Missouri are removed.

c. The entry for Tennessee and all of the material pertaining to Tennessee are removed.

§ 301.52–2a Regulated areas; suppressive and generally infested areas.

* * * * *

Arkansas

(1) *Generally infested area.* None.

(2) *Suppressive area.*

Poinsett County. T. 12 N., R. 5 E.; Sections 22, 23, 24, 25, 26, 27, 34, 35, and 36.

* * * * *

Done in Washington, DC, this 25th day of April 1997.

Charles P. Schwalbe,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–11463 Filed 5–1–97; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. 95–040–2]

RIN 0579–AA73

Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This document amends the regulations pertaining to genetically engineered plants introduced under notification and to the petition process for the determination of nonregulated status. The notification amendments allow most genetically engineered plants that are considered regulated articles to be introduced under the notification procedure, provided that the introduction meets certain eligibility criteria and performance standards. The petition amendments enable the Animal and Plant Health Inspection Service to extend an existing determination of nonregulated status to certain additional regulated articles that are closely related to an organism for which a determination of nonregulated status has already been made. We have prepared guidelines to provide additional information to developers of regulated articles and other interested persons regarding procedures, methods, scientific principles, and other factors that could be considered in support of certain actions under the regulations, and anticipate developing other such guidelines when appropriate for other actions. We are also reducing the field test reporting requirements for certain multi-year field trials conducted under permit or notification procedures.

The amendments simplify procedures for the introduction of certain genetically engineered organisms, requirements for certain determinations of nonregulated status, and procedures for the reporting of field tests conducted under notification. We are also changing all references to ''Biotechnology, Biologics, and Environmental Protection'' to ''Animal and Plant Health Inspection Service'' to reflect an internal reorganization within the Agency.

EFFECTIVE DATE: June 2, 1997.

FOR FURTHER INFORMATION CONTACT: Dr. John Payne, Director, Biotechnology and Scientific Services, PPQ, APHIS, 4700 River Road Unit 98, Riverdale, MD 20737–1237; (301) 734–7602. For technical information, contact Dr. Michael Schechtman, Domestic Programs Leader, Biotechnology and Scientific Services, PPQ, APHIS; (301) 734–7601. Guidelines for extensions to determinations of nonregulated status are available on the Internet at the APHIS World Wide Web site, http://www.aphis.usda.gov/bbep/bp/, or by mail from Ms. Kay Peterson at the address listed above.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR part 340, referred to as the ''regulations,'' pertain to the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms and products that are derived from known plant pests (regulated articles). Before introducing a regulated article, a person is required under § 340.0 of the regulations to either (1) notify the Animal and Plant Health Inspection Service (APHIS) in accordance with § 340.3 or (2) obtain a permit in accordance with § 340.4. Introductions under notification must meet specified eligibility criteria and performance standards. Under § 340.4, a permit is granted when APHIS has determined that the conduct of the trial, under the conditions specified by the applicant or stipulated by APHIS, does not pose a plant pest risk.

On August 22, 1995, APHIS published in the **Federal Register** a proposed rule on Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms and Products (60 FR 43567–43573, Docket No. 95–040–1). This rule proposed to amend the regulations to allow the introduction under notification procedures of any plant species that is not listed as a noxious weed under regulations in 7 CFR part 360, and for release in the environment, is not considered a weed in the area of the proposed release into the environment. In addition, APHIS proposed to increase the range of virus resistance modifications allowable under notification. APHIS also proposed to amend its administrative procedures by discontinuing the requirement that States in every case provide concurrences for notifications for interstate movement prior to APHIS acknowledgment, and to simplify the reporting requirements on the performance characteristics of regulated articles in field trials conducted under permit or notification.

APHIS further proposed to amend the regulations pertaining to petitions for determinations for nonregulated status in § 340.6 to allow the extension of a previously issued determination of nonregulated status to certain additional regulated articles that are closely related to an organism that was determined not to be a regulated article in the initial determination.

To provide information regarding procedures, methods, practices, or protocols, APHIS indicated its intention to prepare guidelines relating to such considerations.

We solicited comments concerning our proposal for 60 days ending October 23, 1995. During the designated comment period, APHIS received a total of 50 comments on the proposed amendments from industry, universities, State departments of agriculture, science policy organizations, environmental groups,

industry organizations, professional societies, consumer organizations, individuals, and a university cooperative extension service office. A general discussion of the comments appears below, followed by a section-by-section response to comments and an explanation of modifications made.

Summary and Analysis of Comments

Over 60 percent of the comments expressed support for the proposed amendments, while about one-third opposed any change in the current level of oversight for genetically engineered organisms. Several commenters, expressing support for the proposed amendments, made detailed comments and suggestions concerning specific provisions and terms used in the proposed amendments. A major concern expressed by commenters in opposition to the proposed simplification of requirements was the potential for an increased risk to the environment from certain transgenic plants, particularly those with wild or weedy relatives. APHIS has carefully considered all the comments, suggestions, requests for clarification, and concerns. Several modifications have been made to the proposed amendments in response to the comments. Before providing detailed responses to comments on specific provisions of the proposed amendments, and an explanation of the modifications made in consideration of these comments, however, APHIS would like to respond in a general way to concern about the potential for increased risk for field trials conducted under notification for certain new transgenic plant species. The comments raising concerns in this regard presuppose that the safety standards enforced by APHIS under its notification procedures are different from those under its permitting procedures. This presupposition is incorrect. The performance standards for field trials under notification procedures, as provided in § 340.3(c), establish the same standards for confinement of regulated articles that have been applied to field trials conducted under permit, except that in the latter the Agency receives and evaluates detailed information on the methodology used to ensure confinement of the regulated articles for each trial. The notification option, which has, to date, been used only with respect to field trials involving six crop species, is one additional means of meeting those standards. More detailed responses to specific comments follow.

Comments on Proposed Changes to Notification Eligibility Criteria (§ 340.3(b))

Approximately half of all comments specifically supported the proposal to revise § 340.3(b)(1) to extend the notification option to any regulated article that is a crop species not listed as a noxious weed in regulations at 7 CFR 360 under the Federal Noxious Weed Act (7 U.S.C. 2801 *et seq.*) and that meets the other eligibility criteria at §§ 340.3(b)(2) through 340.3(b)(6), provided that the regulated article being considered for release into the environment is not considered by the Administrator to be a weed in the area of release into the environment. A representative comment noted that field testing of a wide variety of different types of genetically engineered plants over the past decade has confirmed that such tests can be carried out safely. It further expressed the opinion that the notification system, using performance standards, has worked well since its establishment in 1993.

Another commenter pointed out the importance of simplified procedures to aid the development of improved tree varieties that are propagated as rootstocks under conditions in which they cannot reproduce, produce pollen, or flower, or that are seriously endangered by virulent diseases such as chestnut blight. APHIS agrees with these comments. APHIS notes the experience alluded to in field trials to date under permit with several tree species whose confinement has been assured because the plants were sexually immature, or by physical or biological means. This evidence of safe trials indicates that trials with these species can be conducted safely under notification procedures, and the conduct of such trials should be facilitated by the availability of notification procedures.

About a third of the comments opposed the proposed change to § 340.3(b)(1). In general, comments that indicated specific reasons for opposition to the proposal focused on some or all of the following three issues: the appropriateness of performance standards as regulatory tools for certain field trials; the wide range of species that would be eligible for notification procedures; and the inadequacy of available knowledge about certain aspects of the biology of the plant species or its relatives. Comments pertaining to each of these general topics will be discussed in greater detail below.

Several commenters expressed concern that, by largely shifting oversight for many organisms from permitting to notification procedures, oversight would be inappropriately decreased and compliance could be compromised. One commenter in this regard expressed the view that performance standard-based regulations are typically more difficult to enforce than traditional design standard-based regulations. In response to these concerns, we agree that there is a distinction between performance standards and more prescriptive design standards, and it might in fact be easier, in some instances, to determine whether a design standard, as opposed to a more general performance standard, is being followed. We disagree, however, with the assertion that performance standards are inappropriate when high levels of compliance are desirable. High levels of compliance with a performance standard can be achieved if procedures exist to enable an applicant to meet the standard, and the parameters that determine whether a performance standard is or is not met are clear and well understood.

In the case of implementation of the performance standards under § 340.3(c), it has been useful to provide to individuals seeking to introduce regulated articles derived from any of the six crops listed under § 340.3(b)(1)(i) examples of confinement procedures that would enable the performance standards to be met. Such examples are not prescribed procedures that must be followed, but rather are indications of options that can be used to achieve the required confinement standard for each of the crop species. APHIS has provided such examples in its User's Guide for Introducing Genetically Engineered Plants and Microorganisms (APHIS Technical Bulletin No. 1783)(referred to hereinafter as User's Guide), which is provided upon request to any interested individual. APHIS believes that the same level of clarity can be achieved for other crop species and that providing additional information to responsible persons will remove uncertainty about the ability to comply with the performance standards in particular cases.

APHIS intends that there be clear information available to responsible persons to aid them in meeting the performance standards. To provide additional guidance of this sort, particularly in regard to the requirements of performance standards in §§ 340.3(c)(5) and 340.3(c)(6), APHIS has developed additional information that illustrates the type of reasoning that would apply in designing an appropriate protocol for other crop species based on their biology. The

discussions of biological factors relevant to issues of confinement and persistence for several examples of plant species not included in the original list of crops at § 340.3(b)(1)(i) will be included in a revised User's Guide. The examples will be accompanied by an expanded discussion of the biological factors that need to be considered to evaluate the adequacy of confinement protocols based on the biology of the particular plant species in question.

APHIS has provided advice to responsible persons in the past on whether particular protocols for field tests of the six crops listed at § 340.3(b)(1)(i) meet performance standard requirements. The Agency anticipates providing similar advice upon request for protocols for any other plant species eligible under § 340.3(b)(1). It remains the duty of the responsible person to determine the specific procedures that will need to be used to meet the performance standards and to certify that those standards are being met.

In further response to the commenter, APHIS would stress that the performance standards themselves must not be confused with other mechanisms to monitor or document compliance with those standards. Since the original publication of 7 CFR 340 (52 FR 22892–22915, June 16, 1987), APHIS has performed field inspections for many field trials. Initially, when only permitting procedures were available, inspections were performed exclusively on field trials under permit. Since 1993, many inspections have also been performed on trials that have gone forward under notification procedures. Inspections have often been conducted with the participation of State regulatory officials. These inspections have demonstrated to the Agency that applicants have been able to comply extremely well with either the performance standards or specified permit conditions.

APHIS considers as erroneous the assumption that oversight under permitting procedures provides greater assurance of ''safety'' than oversight under notification procedures. Compliance with either specified permit conditions or performance standards under notification procedures requires the cooperation of all involved in the conduct of the field trial. The outcome of either permitting or notification procedures is attainment of essentially the same level of confinement. No change to the regulations is made in response to this comment.

Several commenters expressed the view that the proposed expansion of eligibility requirements for notification was too broad and that permitting procedures should remain in force for a regulated article that has wild relatives in the United States with which the plant can interbreed. Genetically engineered varieties of crops such as sunflowers, radishes, rice, and rapeseed, which can hybridize with wild relatives growing in the United States, were singled out as special concerns, as were genetically engineered varieties of perennial landscaping species and largely undomesticated species such as forest trees. In response to these concerns, APHIS agrees that there are important differences in the biology of different crop species that will affect the ability of confinement procedures to achieve the required performance standard. These biological factors will be relevant when a protocol intended to meet the performance standards for a particular field trial is being designed. Such factors include, for example, the lifespan of the plant species in the field, dormancy of its seeds, pollen survival and dispersion, the presence of sexually compatible plants that are available to receive pollen in the vicinity of the trial, the ability of the plant to be vegetatively propagated, and climatic conditions. We note, however, that these commenters appear to presume that all gene transfers pose risks, even those that only result in progeny that do not persist in the environment (in accordance with the requirements of performance standards in §§ 340.3(c)(5) and 340.3(c)(6)). We believe that this is not the case. Indeed, it would be inaccurate to assert that any trait that is transferred from a transgenic plant to a wild relative, even with the potential of persisting in a population of that wild relative, will necessarily pose a risk per se. The environmental analysis to address the effect of a particular trait on a recipient population, as required in the consideration of certain petitions for the determination of nonregulated status, would likely involve case-by-case analysis based on the trait, the characteristics of the recipient population, and other factors.

The inference of previous commenters that field tests with certain plant species will require more stringent confinement procedures to comply with the performance standards is, however, clearly correct. Certain crop species are not highly domesticated, and some, such as strawberries, are sometimes grown in areas where interfertile wild relatives are abundant. In some instances these wild relatives are routinely found within fields of the cultivated crop. In such instances, it may be necessary to prevent flowering or to apply physical methods that contain pollen flow. In some instances, the responsible person may deem a particular test site unsuitable for a particular field trial based on such biological considerations. We would, however, note that field trials of many species of trees, which were raised as a concern, can easily be safely performed over a period of several years under notification procedures, based on the fact that the trees do not become sexually mature for a considerable, and well-established, period of years. Other tree species can be effectively isolated from wild populations by the appropriate choice of test location or by use of physical methods for confinement of pollen. APHIS does not believe, therefore, that the biological differences discussed in these comments provide adequate justification for limiting the application of performance standards to a smaller set of host organisms than was in the proposed rule. However, APHIS recognizes that there are two features of biology of trees (and, in some instances, of other crops grown as perennials) that merit specific consideration in a regulatory context. Field tests involving trees may be several years in duration, and such trials may result in unexpected exposures of nontarget organisms in the environment of the test site if continual vigilance as to adherence to performance standards is not maintained. Furthermore, the regulated articles may reach sexual maturity considerably after initial planting. It may well be, therefore, that the procedures utilized to ensure reproductive confinement of the regulated articles in the first year of a field trial may prove inadequate at a later time in the trial. To emphasize the level of continual vigilance that is required to ensure that all relevant biological factors are taken into account, APHIS will require that all field trials under notification procedures that are to be greater than one year in duration be renewed annually. This will be accomplished by adding the following sentence at the end of § 340.3(e)(4):

> Such acknowledgment will apply to field testing for one year from the date of introduction, and may be renewed annually by submission of an additional notification to APHIS.

APHIS stresses that it views the requirement for compliance with a performance standard as a stringent one that requires responsible persons to take a level of care equal to or greater than that under permitting procedures. We expect that, if a responsible person has any question about whether he or she

can comply with the performance standards for the introduction of a regulated article, that person must either apply for a permit under § 340.4 or consult with APHIS; and that States will continue to provide input to APHIS, particularly if they have any concern about whether the performance standards can be complied with in a given field trial.

Another commenter that opposed the proposed extension of notification procedures asserted that APHIS' 1993 final rule (58 FR 17044–17059, March 31, 1993) establishing notification procedures for field trials of certain regulated articles, particularly the six crop species listed in § 340.3(b)(1)(i), was based primarily on a USDA finding that the six listed crop species posed a negligible risk of gene flow to wild relatives in the United States. The commenter argued that in many cases, scientists do not know the extent to which U.S. crops interbreed with wild relatives nor the extent to which wild relatives exist in areas where crops are grown, and further recommended that case-by-case risk assessments under its permit procedures of all U.S. crops with interbreeding wild relatives in this country should continue to be required until the Department has a comprehensive database of information addressing relevant biological factors for these crops.

In response to this comment, APHIS disagrees with the assertion that the primary basis for our final rule establishing the notification option was an Agency determination that there was negligible risk of gene flow from transgenic derivatives of the six listed crop species to wild relatives. Our action was based on accumulated experience showing that the six listed crop species, which were those crops for which the greatest number of field trials had been performed in the United States to that time, could be safely field tested under permit, and on our recognition that the conditions imposed under permit formed the basis for adequate confinement measures under performance standards. In response to a specific request by a commenter, APHIS did provide in its final rule additional evidence that the potential for gene flow from the six listed crop species to wild relatives in the United States was negligible regardless of whether the performance standards were applied. Nevertheless, the Agency continues to believe that the performance standards themselves adequately address the issue of gene flow. APHIS acknowledges that insufficient data with respect to interbreeding potential or the locations of populations of wild relatives for some plant species could affect the appropriateness of design protocols for particular field trials. These considerations would be a necessary part of the responsible person's analysis of what would be required to comply with the performance requirements under § 340.3(c). It may be the case that in some instances, based on the realization that existing information is inadequate, adherence to the performance standards might require, for example, that flowering of the regulated article be prevented or that physical means such as bagging be utilized to prevent pollen flow from the regulated article. As indicated previously, APHIS will consult with responsible persons upon request regarding compliance with the standards in individual instances and is also preparing other useful information for inclusion in its User's Guide. Nonetheless, APHIS believes that the performance standards themselves adequately address the concerns raised by the commenters. No change to the regulations is made in response to this comment.

The commenter does raise a point that is relevant to another section of the rule, however. Incomplete data regarding compatibility with relatives or the presence of interbreeding populations of related species may dramatically affect the ability to reach a subsequent determination of nonregulated status for certain regulated articles, and this should be noted by any persons who may consider submitting such petitions. For traits potentially related to plant survival, such as disease or stress resistance, information of this kind will often be important to an analysis of the potential for plant pest risk under the petition process at § 340.6.

Several commenters disputed APHIS' assertion in the proposed rule that the Agency has gained considerable experience with field testing under notification and permitting procedures. These comments, in general, questioned how much experience had really been gained, in view of the fact that most of the permits have been granted in the last few years; whether the long-term effects of releases had really been determined; and whether the Agency had yet obtained any ''hard data'' to assess specific environmental impacts.

In response to these comments, APHIS believes that its statements regarding accumulated experience remain correct. While it is true that the majority of field trials of regulated articles have been conducted in the last two years, all evidence obtained to date, including that from monitoring reports submitted to the Agency by responsible persons overseeing the tests, indicates that the trials have been conducted safely, and that there has been no reason to believe that any hypothetical ''long-term'' impacts have arisen or are likely or foreseeable as a consequence of the conduct of any field trial in accordance with this final rule. The request for ''hard data,'' which APHIS interprets to mean ''data derived from experiments designed specifically to address particular safety concerns,'' ignores a great deal of highly relevant data, some of which may be empirical in nature, on the behavior of the test plants as determined by individuals expert in the behavior of the plant species. Moreover, ''hard data'' has been requested and obtained by the Agency in some instances, when deemed material to consideration of a petition for determination of nonregulated status for a regulated article.

One commenter inquired whether an applicant would be able to request a permit for which an environmental assessment is written for a regulated article that might qualify for notification procedures. APHIS agrees that field trials that would qualify for notification procedures could be given permits upon request. However, as indicated in APHIS' National Environmental Policy Act (NEPA) Implementing Procedures, which were published on February 1, 1995 (60 FR 6000–6005) and codified at 7 CFR part 372, permitting and acknowledgment of notifications for confined field releases of genetically engineered organisms have been categorically excluded from the requirement to prepare environmental assessments or environmental impact statements. There are two relevant exceptions indicated in those procedures. Section 372.5(d)(1) provides for preparation of an environmental assessment or environmental impact statement ''When any routine measure, the incremental impact of which, when added to other past, present, and future actions (regardless of what agency or person undertakes such actions), has the potential for significant environmental impact.'' Section 372.5(d)(4) provides for the preparation of such analyses ''When a confined field release of genetically engineered organisms or products involves new species or organisms or novel modifications that raise new issues.'' The decision as to whether either or both of these exceptions to the categorical exclusion applies will be made by the Administrator.

One commenter asked whether the proposed changes to notification procedures would in effect require a responsible person to submit requests

for notification more than 120 days in advance of a desired field trial in order to give the Administrator, APHIS, time to determine whether the plant species in question is considered a weed in the area of the proposed introduction, and to give the responsible person time to submit a permit application if notification procedures are deemed not to apply. APHIS believes that the scenario described will rarely apply for plant species that are commonly cultivated. In most instances, there will not be any uncertainty beforehand as to whether a particular species is a weed in the area around the site of a proposed introduction. If an applicant has any uncertainty regarding the weed status of a particular species around the site of a proposed introduction, that applicant should consult with the Agency as early as possible to enable the agency to obtain the necessary information early enough to prevent undesirable delays. It should be pointed out that applicants need to take into consideration the presence of sexually-compatible populations of the same plant species, even if not weedy, in the area of a proposed test site in the development of test protocols that would meet the performance standards under § 340.4.

One commenter suggested that the phrasing of the new eligibility criterion under proposed § 340.3(b)(1) would require that notification procedures apply for introductions of all non-weed plant species. APHIS believes that this comment is incorrect. The eligibility criterion, as written, applies only to regulated articles, as defined under § 340.1.

Less than half of all comments specifically addressed the proposed revision of eligibility criterion under § 340.3(b)(5), which would extend the existing eligibility criterion to allow introductions under notification procedures of plants containing genetic sequences from plant viruses that are noncoding regulatory sequences of known function, or that are sense or antisense genetic constructs derived from viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, and that do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus.

One comment from a scientific society expressed the view that the proposal was based on sound scientific data dealing with the safety of virus-resistant plants. Another comment supported the proposed extension, but recommended in addition that the eligibility criterion not require that any viral gene be derived from a plant virus that is prevalent and endemic in the area where the introduction will occur. The rationale provided for this recommendation was that when field trials are performed under controlled circumstances, the crop performance standards would be sufficient to prevent the unintentional dissemination of the virus by the introduced viral component, which is not itself capable of plant infection. Also, it was indicated that the opportunity for recombination would be less in an isolated field with no homologous viruses than in an area with like viruses.

APHIS disagrees with the commenter's rationale for further changes to the proposal. The performance standards are designed to prevent persistence of the regulated article or its progeny, and do not specifically address dissemination or persistence of other organisms, such as viruses or their vectors.

Approximately a quarter of the comments opposed the proposed revision to the eligibility criterion in § 340.3(b)(5). These comments raised some or all of the following four issues: risks of gene flow to related plant species; risks of synergistic effects when the regulated article is infected with plant viruses other than the one from which its viral component was derived; risks that new viral strains will be produced; and the supposed paucity of empirical data available to support the proposed revision.

One commenter expressed concern that movement of genes of viral origin from regulated articles to related plant species could occur when plants containing such genes are introduced under notification, which could have significant implications for both agroecosystems and natural ecosystems, as viral transgenes transferred to wild plant populations could result in new or worse weeds in farmers' fields or alter the genetic diversity of natural ecosystems.

APHIS disagrees with these comments. APHIS believes that it has addressed the issue of gene flow from regulated articles to other plants in its general discussion of the appropriateness of the performance standards for confinement of field trials.

The issues with respect to potential synergistic effects and/or recombinational events revolve around potential interactions between the regulated article and other viruses in field settings. Before discussing these phenomena in detail, however, APHIS notes that during field testing of virus resistant plants (whether transgenic or conventionally bred), researchers routinely make efforts to exclude unwanted viruses to which the test plants are not resistant (unless they are specifically investigating an effect such as synergy). This is done because infection of plants with other viruses causes additional disease symptoms that make comparative evaluation of the desired disease resistance phenotypes of the test lines (the transgenic lines) with controls (the nontransgenic parent lines) difficult or impossible. The need for exclusion of other viruses during field trials with vegetatively propagated plants (e.g., potatoes) is even more severe. With such plants, infection with other viruses not only contaminates the experimental plants but results in infection of all clonal progeny. Infected plants then need to be destroyed, or the unwanted virus must be eliminated via tissue culture, a time-consuming and expensive procedure. For any crop, if an unwanted virus is seed transmitted, progeny lines also become infected, which can affect an entire breeding program. Thus, researchers have long recognized the importance of minimizing the presence of unwanted viruses from field tests of virus resistant plants. Minimizing unwanted viruses in a test plot minimizes the opportunity for recombination or synergy.

The concerns raised over the potential for synergistic effects between viral genes in the regulated article and other viruses that may infect the plant allude to the phenomenon that, when two viruses simultaneously infect a plant, disease symptoms can be more severe than when either of the viruses alone infects the plant. Such synergistic infections can often result in severely diseased, unsalable crops under current agricultural production. APHIS believes, however, that such synergistic interactions are relatively rare in mixed viral infections. APHIS estimates that more than 2000 plant viruses have been identified worldwide. Information gathered for APHIS on the occurrence of synergistic interactions by Dr. Vicki Vance, University of South Carolina, on file in the administrative record, identified no more than 25 synergistic viral interactions. Moreover, because synergy, unlike recombination, is not related to the potential for creation of new viruses, the effects of synergy may in effect be considered to be agronomic, rather than environmental. Investigation of the potential for synergy may be a part of the evaluation of a new crop variety undergoing agronomic testing. Were synergistic interactions manifested by a transgenic crop during field testing, severe infection would result, and the plants or plant lines would likely be

destroyed because they would have no use in a breeding program. These effects would be limited to the test plants.

Three other independent reports prepared in different countries and published in 1995 and on file in the administrative record address the subject of synergy and viral resistant transgenic plants:

1. ''Transgenic virus-resistant plants and new plant viruses,'' a report prepared by the American Institute of Biological Sciences (AIBS), based on a workshop convened by AIBS and sponsored by the USDA;

2. ''Risks to the Agricultural Environment Associated with Current Strategies to Develop Virus Tolerant Plants Using Genetic Modification,'' written by Henry, C. M., Barker, I., Pratt, M., Pemberton, A. W., Farmer, M. J., Cotten, J., Ebbels, D., Coates, D., and Stratford, R., for the United Kingdom Ministry of Agriculture Fisheries and Food; and

3. ''Transgenic plants expressing viral genes: Issues related to field releases,'' written by Rochon, D. M., Ellis, P. E., Martin, R. R., and Sanforn, H., for Agriculture and Agri-Food Canada.

All these reports support APHIS' conclusions that viral synergies are rare and would pose only transitory agronomic concerns, but not environmental risks. Agronomic characteristics such as disease susceptibility are routinely evaluated during agronomic testing. On the basis of all the information presented, therefore, APHIS believes that the potential for viral synergies when regulated articles are introduced under notification will pose no concerns different from those arising under traditional agricultural breeding and practice.

In further response to the commenters, the issue with respect to recombination centers around the potential to create new plant viruses when transgenic virus resistant plants are infected by other plant viruses. The term ''recombination'' is typically defined as an exchange of nucleotide sequences between two nucleic acid molecules. Such exchanges between genomes result in heritable, permanent change. While recombination is a common process, which is responsible in nature for much of the observed variation between individual members of the same species, a variety of factors affect the appearance and survival of recombinant types. In all experiments that have been performed to date with plant viruses, recombinant types have been observed only when transgenic plants, containing viral sequences and susceptible to the virus from which those sequences are derived, are infected with a defective but replication-competent parental virus type under a strong selection for production of recombinant virus. Recombination between two plant viruses under natural field conditions has never been reported and may be sufficiently rare that it may only be observed to occur on an evolutionary time scale. There are no published reports demonstrating recombination between a virus-resistant transgenic plant and a nondefective and unrelated plant virus. Resistance to an infecting virus would prevent or at least partially inhibit replication of that virus and replicated progeny viruses might not therefore be available for recombination with the resident viral transgene. The reports cited above on transgenic plants expressing viral genes provide more detailed discussions on the factors affecting recombination, the detection or survival of recombinants, and provide additional reference sources.

The likelihood that a statistically rare recombinational event will occur depends on, among other things, sample size. Typically, the first field trials of regulated articles containing genes from plant viruses that have not yet been demonstrated to confer virus resistance on the host plant are small, i.e., with single genotypes representing perhaps 0.5 acre or less. Lines that are selected for testing on larger plots are generally those that have been shown to be resistant to infection by the parental virus under field conditions during prior small scale field testing. In fact, greater than 95 percent of the individual field tests of virus resistant plants that have been conducted to date under permit or notification procedures have been small, under 5 acres in area. The larger field trials that have been performed to date have involved lines that have been subsequently deregulated (e.g., Asgrow's ZW–20 squash) or other crop lines that are relatively far along in their agronomic testing. All such varieties have already been demonstrated to be resistant to viral infection, reducing the likelihood of recombination with the related virus.

As stated above, if an unwanted virus infects the transgenic plant and replicates, recombination theoretically could occur. The potential for recombination will be limited by efforts to exclude unwanted viruses from field tests. Additional constraints in proposed eligibility criterion § 340.3(b)(5) for viral sequences that meet notification are that the inserted viral sequences come from a viral strain that infects the recipient plant and that the virus be widely prevalent in the area where the field test is to be performed. If these limitations apply, the RNA's of concern that could potentially recombine (the viral transgene and the unwanted virus) would be nucleic acids that would have already had the potential to interact and recombine in nature if the two viruses naturally infected the same plant and were located within the same plant tissues.

APHIS believes that scientific evidence, routine agricultural practices, and the other restrictions contained under revised § 340.3(b)(5) make it highly unlikely that any new virus will arise as a result of field testing of a transgenic virus resistant plant under notification procedures. APHIS also believes that in the unlikely event that a new virus should arise, standard practices that are used to control new viral diseases that are detected in agricultural settings would also be adequate to address any new virus. Again, two of the above-cited reports that addressed this general subject reached conclusions similar to those of APHIS. In a report to Agriculture and Agri-Food Canada, Rochon et al. (1995) conclude, ''It is likely that current means of detecting and controlling new diseases in this country would be adequate to control any new virus resulting from recombination between a transgene and another virus.'' The AIBS report concludes by stating, ''With or without the use of transgenic plants, new plant virus diseases will develop that will require attention.'' No changes to the regulations are made in response to these comments.

Several commenters expressing opposition to the proposed revision to § 340.3(b)(5) asserted that there is insufficient empirical data for its justification. In response to these comments, we understand the desire for additional experiments specifically designed to increase understanding of the mechanisms involved in virus resistance, to measure the frequency at which certain interactions between regulated articles and infecting viruses occur, and to examine the effects of those interactions on virus populations. We agree that such information will probably be scientifically interesting. It may also be potentially useful for resolving uncertainties that may arise for specific crop-gene combinations when, eventually, approval is sought to grow the regulated articles under routine agricultural conditions as opposed to under performance standards (i.e., when a petition is submitted to APHIS for a determination of nonregulated status). A statement in the AIBS report (1995) previously cited recognizes this fact: ''More research is

needed to explain these mechanisms and to assess the environmental and agricultural risks that might be presented by the commercialization of transgenic virus-resistant crops.''

We do not agree with the comment that additional data of these types are needed to justify the proposed modification to § 340.3(b)(5) for field trials under notification procedures. Such arguments, APHIS believes, ignore the weight of experience with conventionally bred and conventionally cross-protected crop varieties (a cross-protected variety being one made immune or resistant to a severe strain of a virus by infecting the variety with a mild strain of the virus), and take note of neither the performance standards under § 340.3(b) nor the agricultural practices routinely used to minimize infection of test crops or to control infections.

One commenter suggested that APHIS mischaracterized the results of the AIBS Workshop on Transgenic Virus-Resistant Plants and New Plant Viruses. The comment asserted that a discrepancy exists between the proposed regulations (which would extend eligibility to all viral genes derived from certain viruses, apart from those genes encoding noncapsid movement proteins) and the written proceedings, which in the view of the commenter indicated that any as yet undiscovered viral genes would pose novel risks, with the implicit implication that such genes should not be eligible for APHIS' notification procedures.

APHIS disagrees with this commenter's interpretation of the workshop proceedings. The relevant phrase in the AIBS report, which contains the only mention of ''known'' genes, is, ''The participants agreed that the risk considerations for coat protein (currently on the list for notification) are the same as those for other known viral genes . * * *'' APHIS believes that the report does not attempt to indicate that other genes would pose new risks, but rather that the participants at the workshop only discussed the potential risks of genes for which scientific information was at hand. APHIS believes that enough information has been established to date about the function of plant virus genes so that whole new categories of genes that would raise new concerns other than those addressed at the workshop are unlikely to appear. However, should any information arise that would suggest that notification procedures are not appropriate for a specific, as yet undiscovered class of viral genes, APHIS would of course act to ensure that appropriate safety requirements for field testing applied to such trials.

The comment also noted that the proposal would extend notification procedures to field trials of any size, while the report only discussed risk considerations for small-scale trials, i.e., those under 10 acres. APHIS agrees that the workshop participants, in discussing specific categories of genes in accordance with questions distributed to participants to help focus discussions, specifically addressed small scale field trials. However, in their discussions of the various types of viral interactions (such as recombination and synergy) that formed the broader issues at the heart of the workshop, no specific size-related concerns were raised. Moreover, as was discussed previously, preliminary field trials with new crop lines carrying virus-derived genes are generally conducted on a very small scale until it can be demonstrated that the new lines exhibit the desired virus-resistant phenotype. When this phenotype is manifested, the likelihood that the viral transgene could recombine with a related infecting virus is further limited. Again, however, the general concerns raised are concerns that may become relevant on a case-by-case basis when the Agency considers petitions for determination of nonregulated status for specific virus-resistant regulated articles. No change is made to the regulations in response to this comment.

Comments on Proposed Simplifications to Paperwork Requirements by State Regulatory Officials (§ 340.3(e)(1))

About one-fifth of all comments specifically addressed the proposal to eliminate the requirement that States actively provide to APHIS concurrence on interstate movements of regulated articles under notification. All but one of the comments were in favor of the rule as proposed. Each of those, however, suggested that the proposal needed some additional clarification: either that States' roles in oversight over other aspects of the notification process should be lessened, or that the notification process for interstate movement should be made ''generic'' by indicating a master list of potential terminal destinations to which transgenic seed might be shipped. Several comments indicated that State involvement should be eliminated entirely.

In response to these comments, APHIS believes that the notification process for interstate movement is not burdensome, that State notification and involvement in that process has been, and continues to be, useful, and that it is appropriate that States be made aware that shipments of specific regulated articles may be destined to enter. States should be offered the opportunity to consider any notifications in view of local requirements. APHIS further believes that a system for generic identification of sites to which transgenic seed may be shipped might not provide States with adequate opportunities to address these considerations.

One State commenter indicated strong opposition to removal of the requirement for review and concurrence by affected States. The comment asserted that notification without the review opportunity would not be acceptable. APHIS believes that this comment reinforces the view of other comments, in favor of the proposed rule, that indicated the need for additional clarification. APHIS believes that the proposed regulation was not sufficiently clear in indicating that States would be notified and that those States that wish to continue to review notifications for interstate movement would be free to do so. Furthermore, the important role that States have played in considering local factors with respect to field trials will remain unchanged. (These field test factors, as indicated by one State Department of Agriculture, include review of proposed uses of challenge organisms, the planting of species in areas in which host-free periods exist for the crop, the planting of crops in protection districts where specific state regulations restrict planting, and the planting of plant material for which there are established specific quarantines.) In response to comments, APHIS is revising § 340.3(e)(1) of the regulations to clarify its intent as follows:

> APHIS will provide copies of all notifications to appropriate State regulatory official(s) for review within 5 business days of receipt. Comments to APHIS from appropriate State regulatory officials in response to notifications for interstate movement of regulated articles will not be required by APHIS prior to acknowledgment, although States may provide their reviews to APHIS at their discretion.

Comments on Proposed Changes to Regulations for Petitions for Determination of Nonregulated Status and on Proposed Use of Guidelines To Provide Information to the Public (§ 340.6(e) and Footnotes Added to the Ends of the Headings of §§ 340.3, 340.4, 340.5, and 340.6)

Two related portions of the proposed rule, i.e., the proposed changes to regulations for petitions for determination of nonregulated status and the proposed use of guidelines to

provide information to the public on various issues, were frequently discussed together in comments. APHIS will discuss the comments received on these two topics together.

A majority of comments that specifically addressed the expansion of determinations of nonregulated status supported the concept of relating the extension of a determination of nonregulated status to a determination of nonregulated status for a closely related antecedent organism. One comment stated that the slight differences in closely related varieties are no more significant than the differences that occur between the products of traditional plant breeding.

Several commenters also noted the value of the increased flexibility provided by the proposed changes, in allowing for desirable outcomes such as greater innovation, reduced paperwork, less redundant experimentation, and promoting the rapid development of the best new crop varieties. One commenter, in pointing out that progress through the development of new transformants would be encouraged under the proposed changes, noted that the current system encourages the development of genetically engineered crops using a trait from a single progenitor line, and that such crops are genetically more narrow and less adaptable than crops developed from several lines derived from various insertions of the same trait. APHIS agrees with these comments.

The comments opposed to the proposed extension of determinations of nonregulated status to plants closely related to antecedent organisms generally expressed the view that a ''huge loophole'' would be opened up under which risk assessments of potentially dangerous new varieties would not be made. One comment suggested that companies would be able to reengineer particular plants to contain genes that pose ecological concerns and then claim that the new plants are, indeed, ''closely related.''

APHIS disagrees with these comments. The basis for extending a determination of nonregulated status to additional closely related regulated articles will be a demonstration by the applicant that the risk assessment that was developed for the antecedent organism is in fact adequate to address any potential plant pest risk issues for the regulated article. While the guidelines developed by APHIS will provide examples of types of differences between regulated article and antecedent organism that the Agency believes are unlikely to raise such new issues, it will be the burden of the applicant to provide data, including data from field tests, to demonstrate this contention. Moreover, in the proposal, any action by the Agency to extend a determination of nonregulated status would not take effect for 30 days. This interval was deliberately incorporated into the proposed rule to allow an opportunity for any new plant pest risk issues that might have been overlooked in APHIS' review of the applicant's requests to be identified. No change to the regulations is made in response to these comments.

Another commenter, expressing the desire that APHIS proceed cautiously with respect to this proposed action, noted that differences in gene insertion sites, copy number, and genetic background have the potential to make two very similar sounding varieties significantly different in phenotype. APHIS agrees that phenotypic differences may arise in these ways. However, the Agency believes that the differences that may result would likely be of the magnitude observed through traditional crop breeding. In any event, the phenotype of the regulated article will need to be specifically described in any request for an extension of an existing determination of nonregulated status. On a case-by-case basis, APHIS will consider whether observed phenotypic changes raise any issues that were not adequately addressed in the determination of nonregulated status for the antecedent organism, and the Agency's decision will be announced to the public 30 days before it takes effect.

One commenter objected to this portion of the proposed rule on the grounds that commercialization of genetically engineered plants raises large-scale issues not addressed by small-scale field testing, and, implicitly, that these issues would not be adequately addressed when requests for extension to existing determinations of nonregulated status are considered. APHIS disagrees. We reiterate, as was indicated in response to comments in the final rule establishing the notification and petition options, that we believe that all relevant issues are carefully considered in APHIS analyses of petitions for determination of nonregulated status. It should further be noted that other agencies outside USDA, notably the Environmental Protection Agency and the Food and Drug Administration, also exercise regulatory responsibilities for assuring the safety of certain agricultural products developed using biotechnological techniques. The framework of agency authorities and responsibilities, under which more than one agency often has a designated regulatory role in assuring the safety of a particular product was set forth by the White House Office of Science and Technology Policy as the Coordinated Framework for the Regulation of the Products of Biotechnology (51 FR 23303–23350, June 6, 1986).

Two commenters addressed APHIS' discussion of the use of guidelines as part of regulatory oversight. One comment stated that guidelines should not be used as a substitute for rulemaking, and that the practice of issuing guidelines should be codified in the regulation and not relegated to the status of a footnote in the preamble of the proposed regulation.

Both commenters requested that APHIS codify the use of guidelines to establish the policy that data developed in compliance with those guidelines will be accepted by the Agency for purposes of review. In response to these comments, APHIS notes that its guidelines are intended to provide guidance to applicants as to what kind of information could be or has been submitted and approved by APHIS. This guidance is not a guarantee that any other submission along the same lines will receive the same determination. Each situation will be addressed on a case-by-case basis. Also, the guidelines are not intended to be requirements for submission of requests under this part and, accordingly, they have not been placed in the regulations. Should APHIS at a later date decide to adopt the guidelines as requirements, it would do so after notice and comment rulemaking. In addition, APHIS anticipates that data and information submitted in accordance with the guidelines would generally be acceptable to the Agency, unless additional information becomes available to the Agency that raises specific new plant pest risk issues regarding a particular request for an extension of a determination of nonregulated status. As stated previously, this determination will be made on a case-by-case basis. No change to the regulations is made in response to these comments.

Several comments were received regarding the use of guidelines to help applicants establish the similarity of a regulated article to an antecedent organism. Many of the comments suggested that APHIS needed to provide clear definitions for ''closely related'' and ''negligibly different,'' two terms used in the discussion of the relation of antecedent organism to regulated article in the proposed rule. Two comments indicated that a standard for ''closely related'' should be put directly in the text of the regulations. Several commenters also expressed the desire to

comment directly on precise definitions for these terms or on any guidelines APHIS might develop. Several comments suggested that it was not possible, given the information in the proposed rule, to provide informed comments on this portion of the proposed rule.

In response to these comments, APHIS continues to believe, as indicated in the proposed rule, that it is not appropriate to establish rigid rules or definitions for determining similarity. A wide range of minor differences might be exhibited by a regulated article and its antecedent organism that would not affect any characteristics related to the potential for plant pest risk of the regulated article. Moreover, the relevant plant pest risk issues discussed in any determination of nonregulated status will vary depending on the biology of the regulated article in question. When an applicant requests an extension of a determination of nonregulated status, that applicant must demonstrate that the Agency's analysis of the identified relevant issues for the antecedent organism, in fact adequately addresses all relevant issues relating to the regulated article as well. APHIS has developed guidelines for extensions to determinations of nonregulated status. The Agency believes that these guidelines will provide useful examples of some types of modifications that should not raise new plant pest risk issues, and the kinds of information that an applicant may use in support of such a request. No applicant is required to follow the guidelines, and because an applicant follows the guidelines does not mean his or her request will automatically be approved. Each application will be evaluated on its own merits. The guidelines are available on the Internet or by mail as indicated under **FOR FURTHER INFORMATION CONTACT**. APHIS welcomes suggestions on how to improve the guidelines themselves. The Agency will carefully consider all suggestions, both those that identify specific new plant pest risk issues that may be posed by classes of modifications as well as any of those identifying additional types of similarities that would be unlikely to raise any new risk issues. The guidelines will be updated periodically as extensions are granted.

Several comments indicated general preferences for either stringent or flexible requirements. Four other comments provided specific suggestions as to the types of similarities between antecedent organisms and regulated articles that the commenters believe would be unlikely to raise new plant pest risk issues. APHIS does not believe that it would be informative to attempt to categorize guidance information provided to potential applicants as either ''stringent'' or ''flexible,'' inasmuch as these are subjective terms. We would note that independent of the specific content of the guidelines, the Agency's responsibilities to prevent the introduction and dissemination of plant pests are no less stringent under the regulations in 7 CFR part 340 than under its other regulations. The comments suggested the following types of changes between antecedent organisms and regulated articles would raise no new plant pest risk issues: the regulated article and the antecedent organism contain genes from different donor organisms when the two genes perform the same molecular function; and the antecedent organism and the regulated article differ only in the use of a different selectable marker gene; the antecedent organism and the regulated article differ only in structural modifications of the same functional gene, or in the use of different noncoding regulatory sequences to drive the expression of the gene. APHIS agrees that it is likely that most organisms in the proposed classes would raise no new plant pest risk issues. As an illustration, a new ''selectable marker gene'' could potentially be a gene of any function, providing that a useful assay has been developed for it in the context in which the gene is to be expressed. However, evaluation of the potential for plant pest risk posed by a new selectable marker gene would, APHIS believes, require consideration of the specific function of that gene. A requester will need to provide justification as to why the analysis put forth in the determination of nonregulated status for the antecedent organism is adequate to address any potential plant pest risk issues that may be posed by the regulated article. No changes to the regulations are made in response to these comments.

One State cooperator expressed the view that States need the opportunity to review guidelines to verify that any specific conditions in the State are addressed. The comment asked three questions: (1) how States can make known any difference of opinion on any judgment by APHIS to extend a determination of nonregulated status; (2) whether the particular guideline on which a requester based a request for extension of a determination would be identified in that request; and (3) if a different guideline were followed by a person requesting an extension of a determination of nonregulated status, whether States would have the opportunity to comment on that guideline.

In response to these comments, APHIS notes, first, that it welcomes any comments from its State cooperators at any time, whether in response to any guideline or in response to a particular action to extend a determination of nonregulated status. With respect to the identification of specific guidelines on which an applicant bases his or her request to extend a determination of nonregulated status, APHIS presumes that the applicant will describe in any request, the justification for the proposed extension. An applicant may choose whether or not to follow a particular guideline as a basis for a proposed extension, inasmuch as adherence to the guidelines is not mandatory. APHIS believes that whether any particular guideline may have been followed is not important, but that States should focus on the justification provided by an applicant and the documentation developed by the Agency that demonstrates that the analysis of the antecedent organism is adequate to address the new regulated article as well.

One commenter in favor of the proposal to allow the extension of determinations of nonregulated status to closely related organisms requested that APHIS change the term ''antecedent organism'' to either ''antecedent deregulated article'' or ''substantially equivalent organism,'' to avoid implying that new genetic transformation events result in ''new organisms.'' APHIS does not believe that the term ''antecedent organism'' carries with it the implication that the commenter inferred. No change to the regulations is made in response to this comment.

Two commenters requested that individuals who seek extensions of determinations of nonregulated status and who did not submit the initial petition for determination of nonregulated status be required by APHIS to provide written proof of permission for use of any information in the initial petition. One of those comments further suggested that APHIS should provide petitioners with a means of deriving compensation for information from their petition that is used by another person who requests an extension of the original determination of nonregulated status. If such a compensation provision is not included, then, the comment asserted, extensions of determinations of nonregulated status should only be available to the submitters of the initial petition for the antecedent organism.

APHIS understands the concern that competitors may derive a competitive advantage from utilizing information developed by others without equivalent expenditure of time and money. However, the Agency disagrees that an individual who requests an extension of a determination of nonregulated status will necessarily utilize to any great extent the data contained in the petition for the antecedent organism. Rather, a person who requests an extension to a determination of nonregulated status is likely, in large part, to make reference to APHIS' analysis of the potential for plant pest risk posed by the antecedent organism, providing additional evidence for the new regulated article that the existing analysis is adequate to address that organism as well. Requesters do need, however, to attest to the validity of any data they provide to the agency that is material to the safety of the regulated article that is the subject of the extension request.

Two commenters requested clarification on the content of requests to extend determinations of nonregulated status, specifically on the format of such requests and on information requirements. APHIS does not believe a specific format for requests for extension of determinations of nonregulated status needs to be specified, but believes that the request itself could simply be provided to the Agency in the form of a letter. Similarly, the guidelines, as guidelines rather than regulations, do not specify data requirements in great detail, but indicate the general rationale of the analyses that need to be presented to the Agency and the general areas that need to be addressed, including a description of the genetic modifications in the regulated articles under consideration and a comparison of the modifications in those regulated articles with those in the antecedent organism, information on the phenotypic expression of the genetic modifications in the regulated articles and any known differences in phenotype between the regulated article and its antecedent organism in support of the contention that the regulated articles in question do not pose new risk issues meriting separate consideration.

One commenter requested that APHIS clarify whether field data reports need to be submitted along with a request to extend determinations of nonregulated status. APHIS believes that submission of such data is material to any determination of nonregulated status, whether the determination is made in response to a separate petition or in response to a request for extension of a determination. (The guidelines mentioned previously do indicate that data from at least one field trial should be included for any new regulated articles for which an extension of a determination of nonregulated status is requested.) APHIS intended in its proposed rule that requirements for submission of field data reports for petitions for the determination of nonregulated status under proposed § 340.6(c)(5) would also apply to extensions of such determinations. In response to comments, proposed § 340.6(c)(5) is revised to indicate that field test reports for all completed field trials need to be submitted prior to submission of either a petition for determination of nonregulated status or a request for extension of a determination of nonregulated status.

Two commenters recommended that APHIS eliminate the 30-day interval between the announcement of an extension of a determination of nonregulated status and its effective date, based on the fact that the Agency had already conducted a thorough safety review, with public comment, on the antecedent organism. APHIS believes that it is necessary to retain the 30-day interval to allow State officials and PPQ officers to receive and process the information concerning the extension of an existing determination to new lines. Moreover, § 340.6(e)(3) ensures that the public has adequate notice of all preliminary decisions to extend determinations of nonregulated status by announcing such decisions in the **Federal Register** 30 days before the decisions become final and effective. This section provides that APHIS may modify its preliminary decision should APHIS receive additional information that it determines warrants a change in the decision. In such cases, APHIS will issue a revised decision and publish it in the **Federal Register**. In the absence of additional information that the Agency believes warrants such a change, the preliminary decision will automatically become final and effective after 30 days.

Comments on Proposed Simplifications to Reporting Requirements Under Permit or Notification (§§ 340.3(d)(4), 340.4(f)(9)), and 340.6(c)(5))

About 40 percent of the comments specifically addressed the proposals to simplify the reporting requirements under permit and notification procedures in §§ 340.3(d)(4), 340.4(f)(9), and 340.6(c)(5). Less than half of the comments on this section supported the proposal. These supportive commenters recognized the intent of the proposed regulations to preserve reporting of all significant occurrences, in that the proposed regulations would still require: reporting of deleterious effects observed in trials under either permit or notification procedures; and submission of all field test reports for completed trials prior to, or as part of, a petition for determination of nonregulated status.

A majority of those who commented on this section opposed the proposed simplification of reporting requirements, although a few of those commenters indicated that other, more limited streamlining measures would be appropriate. Several commenters suggested that field reporting requirements should be strengthened, although no evidence in support of such a view was provided.

Commenters opposed to the proposed regulations and in favor of retaining existing reporting requirements or of implementing other, more limited measures, provided justification for their disapproval of the proposed changes to the regulations. One commenter suggested that even though there have been no unfavorable incidents with the few organisms released to date, other future releases might not be as safe, and that there has been little long term analysis of the potential environmental effects caused by such releases. A second commenter suggested that USDA created a loophole which would allow companies to decide for themselves what constitutes deleterious effects, and that USDA and the public could be kept in the dark about unsafe field trials. A third commenter stressed the importance of reporting requirements as an incentive for companies to comply with APHIS's record-keeping requirement, in providing information to the public, and in helping generate public confidence in the conduct of field trials.

In response to these comments, APHIS agrees in part with the first comment that it is inappropriate to base judgments on the safety of future introductions of specific regulated articles solely on the behavior of other regulated articles in previous introductions. However, we have never intended that reports of field trial results submitted to APHIS be broadly used to affirm the safety of individual future trials with other organisms. Each report is used in more limited and appropriate contexts that refer specifically to the trial itself, i.e., to verify that specific introduction did not result in unmanaged dissemination of a regulated article, and to document any unusual occurrences during the trial or any deleterious effects of the regulated article on plants, nontarget organisms, or the environment. The reports do support the broad conclusion that it has

been possible to conduct field trials with a variety of plant species under a variety of experimental protocols without unmanaged dissemination of regulated articles, and the reports indicate that to date, observed unusual occurrences and deleterious effects have been minimal. Further, APHIS believes that the suggestion that the Agency should consider potential long term environmental effects that differ from any effects that have yet been observed is outside the scope of the requirements of the NEPA and would be an exercise in speculation. NEPA does require, however, that Agencies have a continuing duty to gather and evaluate new information relevant to the environmental impact of their actions (*See* Association Concerned About Tomorrow v. Dole, 610 F.Supp. 1101 (D.C. Texas 1985)).

APHIS also disagrees with the second comment that the proposed simplifications of reporting requirements create a ''loophole'' for the reporting of deleterious effects. The proposed regulation neither alters in any way the legal requirement that deleterious effects be reported to the agency, nor alters either the classes of effects that are to be reported to the agency or the time schedules for reporting those effects. The proposed rule would only have eliminated the requirement for submission of field data reports for field trials conducted under notification procedures if those trials exhibited no deleterious effects, unusual occurrences, or accidental releases. Any events or observations of deleterious effects, unusual occurrences, or accidental releases would have been reported to APHIS and the reports would have been available for public scrutiny. If a responsible person had any uncertainty regarding whether a particular event or observation constituted a deleterious effect, unusual occurrence, or accidental release, it was their responsibility to contact APHIS to ascertain whether that event or observation required reporting under the proposed regulations.

In response to the third comment, APHIS disagrees that the requirement to submit field data reports for trials under notification procedures in which no deleterious effect, unusual occurrence, or accidental release is observed, in fact provides any additional incentive to maintain complete and accurate records. However, the Agency agrees that the availability of field trial reports, including the vast majority not reporting unexpected events, may help to increase public confidence about the conduct of field trials. For this reason, we believe that there is significant benefit in maintaining reporting requirements for all field trials under notification or permit procedures at the present time. The Agency will accordingly continue to require submission of field data reports for all field trials. The regulations at § 340.3(d)(4)(i) are changed in response to these comments.

Inasmuch as the proposal did not affect recordkeeping requirements, we believe that a continued requirement for submission of field data reports is not a great burden on responsible persons. APHIS received two identical comments that opposed the original proposal for streamlining reporting requirements. Both comments requested that, for field trials of longer than one year duration, the requirement for yearly submission of field data reports be eliminated and that only a single report be submitted within 6 months of completion of the field trial. APHIS believes that this is a reasonable request. In response to these comments, the regulations at §§ 340.3(d)(4)(i) and 340.4(f)(9) are changed accordingly. Additionally, the regulations at § 340.6(c)(5) for the submission of yearly field data reports in multi-year field trials in support of petitions for determination of nonregulated status are changed to be consistent with the previous sections.

Another commenter suggested that when APHIS receives field test reports that demonstrate deleterious effects or other unexpected field observations, the agency should be required to notify the affected State of those observations. APHIS agrees that affected States should be informed when such events are observed. Such provision of information is in keeping with our existing coordination with States. APHIS currently provides such information to States on a routine basis, and will continue to inform affected States in the future whenever the Agency receives either a report of deleterious effects or directly notify States under § 340.4(f)(10) that there has been an accidental or unplanned release.

Miscellaneous

We are deleting all references to ''Biotechnology, Biologics, and Environmental Protection'' and replacing them with ''Animal and Plant Health Inspection Service'' in order to reflect an internal reorganization within APHIS; we are also adding a definition of *Administrator* as part of that change. The authority citation has also been amended to reflect number changes in Title 7 of the Code of Federal Regulations that address delegations of authority to the Assistant Secretary, Marketing and Regulatory Programs, and the Administrator, APHIS.

Therefore, based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposal as a final rule with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.[1]

The effect of the amendments is to simplify procedures: (1) For the introduction of certain genetically engineered organisms by expanding the scope of organisms that will be included under notification procedures and lessening certain administrative requirements for State concurrence on interstate movements under notification procedures; (2) for determination of nonregulated status for certain organisms by allowing for extension of determinations of nonregulated status to other regulated articles closely related to those for which the initial determination was made; and (3) for reporting requirements during multi-year field trials.

The expansion of the scope of organisms included under notification procedures will eliminate the need for a permit to conduct field tests for many crops that currently fall under the permitting regulations. This will allow researchers to conduct field tests for most crops with greatly simplified regulatory requirements. At present, approximately 87 percent of all field trials are conducted under notification procedures. Based on trials to date, APHIS estimates that less than 0.5 percent of the transgenic plants field tested would not qualify for notification procedures based on the local weed status of the crop species. In addition, nearly 99 percent of all introduced genes in plants field tested to date have qualified under notification procedures. Most of the donor genes that have not met the eligibility criteria have been virus-derived genes that could

[1] The agricultural biotechnology industry is still in a relatively early stage of development. Each year, as the industry continues to grow, it is anticipated there will be growth in experimentation, ultimately resulting in an increase in agricultural production and a broadening of international trade. The potential benefits could be significant, but are speculative at this time. APHIS anticipates that this Final Rule will be generally welcomed by public and private researchers, because it is estimated that it could save the industry as a whole perhaps $50,000 in costs associated with preparing submissions to APHIS. These savings are expected to increase as the number of submissions to APHIS continues to grow.

potentially also qualify for notification under the revised § 340.3(b)(5). APHIS therefore estimates that about 99 percent of all field trials will be conducted under notification procedures under these modifications. APHIS estimates that the cost savings for preparation of notification over preparation of a permit application is approximately 95 percent.

APHIS also estimates that extension of existing determinations will potentially be applicable to perhaps half of all regulated articles for which a determination of nonregulated status might be sought. The amount of time required to establish similarity with an antecedent organism, APHIS estimates, might be about one-fourth of that required for preparation of a petition for determination of nonregulated status. Much of this data is data that the researcher should already have acquired while conducting field tests of genetically engineered crops.

This rule is consistent with the risk-based and product-based philosophy underlying the Federal policy for the regulation of the products of biotechnology, as announced by the Office of Science and Technology Policy in the Coordinated Framework for the Regulation of the Products of Biotechnology (51 FR 23303–23350, June 26, 1986). It is also consistent with the principles of regulation expressed in Executive Order 12866, specifically that the agency consider the degree and nature of risks posed by the activities under its jurisdiction, and tailor its regulations to achieve the least burden on society consistent with obtaining its regulatory objectives. The option of allowing applicants to submit requests to extend existing determinations of nonregulated status to one or more related organisms is also consistent with the Presidential Memorandum to heads of Departments and Agencies of March 4, 1995, on the Regulatory Reform Initiative which, among other things, directs agencies to consider the question, ''Could private business, setting its own standards and being subject to public accountability, do the job as well?''

In response to the comments received, APHIS is changing the proposed regulations to simplify field test reporting for notifications, permits, and petitions, and to clarify the requirement for State concurrence on interstate movements under notification procedures.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This final rule contains an information collection requirement that was not included in the proposed rule. Specifically, this final rule adds an additional 288 annual burden hours required for the field test reports submission to APHIS. In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this information collection requirement has been submitted for approval to the Office of Management and Budget (OMB). When OMB notifies us of its decision, we will publish a document in the **Federal Register** providing notice of the assigned OMB control number or, if approval is denied, providing notice of what action we plan to take.

List of Subjects in 7 CFR Part 340

Administrative practice and procedure, Biotechnology, Genetic engineering, Imports, Packaging and containers, Plant diseases and pests, Transportation.

Accordingly, we are amending 7 CFR part 340 as follows:

PART 340—INTRODUCTION OF ORGANISMS AND PRODUCTS ALTERED OR PRODUCED THROUGH GENETIC ENGINEERING WHICH ARE PLANT PESTS OR WHICH THERE IS REASON TO BELIEVE ARE PLANT PESTS

1. The authority citation for part 340 is revised to read as follows:

Authority: 7 U.S.C. 150aa–150jj, 151–167, and 1622n; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(c).

§ 340.0 [Amended]

2. In § 340.0(a), the introductory text, the words ''Director, BBEP,'' are removed and the word ''Administrator'' added in their place.

3. Section 340.1 is amended as follows:

a. In the definitions of *courtesy permit, inspector, permit,* and *regulated article,* the words ''Director, BBEP,'' are removed and the word ''Administrator'' added in their place.

b. The definition of *Director, BBEP* is removed, and definitions for *Administrator* and *antecedent organism* are added, in alphabetical order, to read as set forth below:

§ 340.1 Definitions.

* * * * *

Administrator. The Administrator of the Animal and Plant Health Inspection Service (APHIS) or any other employee of APHIS to whom authority has been or may be delegated to act in the Administrator's stead.

* * * * *

Antecedent organism. An organism that has already been the subject of a determination of nonregulated status by APHIS under § 340.6, and that is used as a reference for comparison to the regulated article under consideration under these regulations.

* * * * *

§§ 340.4, 340.8, and 340.9 [Amended]

4. In § 340.4, footnotes 5 through 7 are redesignated as footnotes 7 through 9; in § 340.8, footnote 8 is redesignated as footnote 12; and in § 340.9, footnote 9 is redesignated as footnote 13.

5. Section 340.3 is amended as follows:

a. A new footnote 5 is added at the end of the section heading and paragraphs (b)(1), (b)(5), (d)(4), (e)(1) and (e)(4) are revised to read as set forth below.

b. In paragraph (d)(1), the words ''Biotechnology, Biologics, and Environmental Protection'' are removed and the words ''Plant Protection and Quarantine, Biotechnology and Scientific Services'' are added in their place.

c. In paragraph (d)(3), introductory text, the word ''BBEP'' is removed and the word ''APHIS'' is added in its place.

d. In paragraphs (d)(5), (e)(2), and (e)(3), the words ''Director, BBEP,'' are removed and the word ''Administrator'' is added in their place.

§ 340.3 Notification for the introduction of certain regulated articles.[5]

* * * * *

[5] APHIS may issue guidelines regarding scientific procedures, practices, or protocols which it has found acceptable in making various determinations under the regulations. A person may follow an APHIS guideline or follow different procedures, practices, or protocols. When different procedures, practices, or protocols are followed, a person may,

(b) * * *

(1) The regulated article is any plant species that is not listed as a noxious weed in regulations at 7 CFR part 360 under the Federal Noxious Weed Act (7 U.S.C. 2809), and, when being considered for release into the environment, the regulated article is not considered by the Administrator to be a weed in the area of release into the environment.

* * * * *

(5) To ensure that the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, plant virus-derived sequences must be:

(i) Noncoding regulatory sequences of known function, or

(ii) Sense or antisense genetic constructs derived from viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, and that do not encode a functional noncapsid gene product responsible for cell-to-cell movement of the virus.

* * * * *

(d) * * *

(4) Field test reports must be submitted to APHIS within 6 months after termination of the field test. Field test reports shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

* * * * *

(e) * * *

(1) APHIS will provide copies of all notifications to appropriate State regulatory official(s) for review within 5 business days of receipt. Comments to APHIS from appropriate State regulatory officials in response to notifications for interstate movement of regulated articles will not be required by APHIS prior to acknowledgment, although States may provide their reviews to APHIS at their discretion.

* * * * *

(4) APHIS will provide acknowledgment within 30 days of receipt that the environmental release is appropriate under notification. Such acknowledgment will apply to field testing for 1 year from the date of introduction, and may be renewed annually by submission of an additional notification to APHIS.

* * * * *

but is not required to, discuss the matter in advance with APHIS to help ensure that the procedures, practices, or protocols to be followed will be acceptable to APHIS.

6. Section 340.4 is amended as follows:

a. A new footnote 6 is added at the end of the section heading.

b. In paragraph (a), the first complete sentence after the paragraph heading is revised to read as set forth below.

c. Paragraph (f)(9) is revised to read as set forth below.

d. The words ''Director, BBEP'' are removed and the word ''Administrator'' is added in their place in the following places:

i. Paragraph (f), introductory text;

ii. Paragraph (f)(7);

iii. Paragraph (f)(8);

iv. Paragraph (g), each time they appear;

v. Paragraph (h)(1).

e. The words ''Biotechnology, Biologics, and Environmental Protection'' are removed and the word ''APHIS'' is added in their place in the following places:

i. Paragraph (b), introductory text, each time they appear;

ii. Paragraph (c), introductory text, each time they appear;

iii. Paragraph (c)(1), both times they appear;

iv. Paragraph (c)(2);

v. Paragraph (f)(10);

vi. Paragraph (f)(11)(ii);

vii. Paragraph (h)(2);

viii. Paragraph (h)(3), both times they appear.

f. In paragraph (b), in newly redesignated footnote 8, the words ''Biotechnology, Biologics, and Environmental Protection'' are removed and the words ''Plant Protection and Quarantine, Biotechnology and Scientific Services'' added in their place.

g. In paragraph (e), the words ''Biotechnology, Biologics, and Environmental Protection, of the'' are removed and the words ''APHIS of the'' added in their place, and the words ''Biotechnology, Biologics, and Environmental Protection, a permit'' are removed and the words ''APHIS, a permit'' added in their place.

§ 340.4 Permits for the introduction of a regulated article.[6]

(a) * * * Two copies of a written application for a permit to introduce a regulated article, which may be obtained from APHIS, shall be submitted by the responsible person to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Biotechnology and Scientific Services, Biotechnology Permits, 4700 River Road, Unit 147, Riverdale, Maryland 20737–1237. * * *

* * * * *

[6] See footnote 5 in § 340.3.

(f) * * *

(9) A person who has been issued a permit shall submit to APHIS a field test report within 6 months after the termination of the field test. A field test report shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

* * * * *

7. Section 340.5 is amended as follows:

a. In § 340.5, a new footnote 10 is added at the end of the section heading to read as set forth below.

b. The words ''Director, BBEP'' are removed and the word ''Administrator'' added in their place in the following places:

i. In paragraph (a), each time it appears.

ii. In paragraph (c)(3), both times it appears.

c. In paragraph (b), introductory text, the words ''Biotechnology, Biologics, and Environmental Protection'' are removed and the words ''Biotechnology and Scientific Services, PPQ'' added in their place.

d. In paragraph (b), under subheading ''PETITION TO AMEND 7 CFR 340.2,'' the words ''the Director, BBEP of Biotechnology, Biologics, and Environmental Protection, to'' are removed and the words ''that the Administrator'' added in their place.

e. In paragraph (c)(1), in the third sentence, and in paragraph (c)(3), the words ''Biotechnology, Biologics, and Environmental Protection'' are removed and the word ''APHIS'' added in their place.

f. In paragraph (c)(1), in the first sentence, and in paragraph (c)(2), the words ''Director of Biotechnology, Biologics, and Environmental Protection'' are removed and the word ''APHIS'' added in their place.

g. In paragraph (c)(3)(ii), the words ''Director, BBEP's'' are removed and the word ''Administrator's'' added in their place.

§ 340.5 Petition to amend the list of organisms.[10]

* * * * *

8. Section 340.6 is amended as follows:

a. A new footnote 11 is added at the end of the section heading, a new paragraph (c)(5) is added, paragraph (e) is redesignated as paragraph (f), and a new paragraph (e) is added to read as set forth below.

b. The words ''Director, BBEP,'' are removed and the word ''Administrator''

[10] *See* footnote 5 in § 340.3.

added in their place in the following places:

i. Paragraph (a), both times they appear;

ii. Paragraph (b), under subheading ''PETITION FOR DETERMINATION OF NONREGULATED STATUS'';

iii. Paragraphs (d)(1), (d)(2), and (d)(3).

c. In paragraph (a), remove the words ''Director, Biotechnology, Biologics, and Environmental Protection (BBEP),'' and add in their place the word ''Administrator''.

d. In paragraph (b), remove the words ''Biotechnology, Biologics, and Environmental Protection'' and add in their place the words ''Plant Protection and Quarantine, Biotechnology and Scientific Services''.

e. In paragraph (c)(4), remove the word ''Director'' and add the word ''Administrator'' in its place.

f. In paragraph (d)(1), remove the words ''The BBEP'' and add in their place the word ''APHIS''.

g. In the undesignated paragraph following paragraph (d)(3)(ii), remove the word ''Director's'' and add the word ''Administrator's'' in its place, and remove the word ''BBEP'' and add the word ''APHIS'' in its place.

h. In newly redesignated paragraph (f)(1), remove the word ''Director's'' and add the word ''Administrator's'' in its place.

§ 340.6 Petition for determination of nonregulated status.[11]

* * * * *

(c) * * *

(5) Field test reports for all trials conducted under permit or notification procedures, involving the regulated article, that were submitted prior to submission of a petition for determination of nonregulated status or prior to submission of a request for extension of a determination of nonregulated status under paragraph (e) of this part. Field test reports shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

* * * * *

(e) *Extensions to determinations of nonregulated status.*

(1) The Administrator may determine that a regulated article does not pose a potential for plant pest risk, and should therefore not be regulated under this part, based on the similarity of that organism to an antecedent organism.

(2) A person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request shall include information to establish the similarity of the antecedent organism and the regulated articles in question.

(3) APHIS will announce in the **Federal Register** all preliminary decisions to extend determinations of nonregulated status 30 days before the decisions become final and effective. If additional information becomes available that APHIS believes justifies changing its decision, it will issue a revised decision.

(4) If a request to APHIS to extend a determination of nonregulated status under this part is denied, APHIS will inform the submitter of that request of the reasons for denial. The submitter may submit a modified request or a separate petition for determination of nonregulated status without prejudice.

* * * * *

§ 340.7 [Amended]

9. In § 340.7, paragraph (b), the introductory text, remove the words ''Biotechnology, Biologics, and Environmental Protection'' and add in their place the word ''APHIS''.

Done in Washington, DC, this 28th day of April 1997.

Donald W. Luchsinger,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–11359 Filed 5–1–97; 8:45 am]

BILLING CODE 3410–34–P

[11] *See* footnote 5 in § 340.3.

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

7 CFR Part 1755

RUS Standard for Acceptance Tests and Measurements of Telecommunications Plant

AGENCY: Rural Utilities Service, USDA.

ACTION: Final rule.

SUMMARY: The Rural Utilities Service (RUS) amends its regulations on Telecommunications Standards and Specifications for Materials, Equipment and Construction, by rescinding RUS Bulletin 345–63, RUS Standard for Acceptance Tests and Measurements of Telephone Plant, PC–4, and codifying the revised RUS standard at 7 CFR 1755.400 through 7 CFR 1755.407, in the Code of Federal Regulations. The revised standard: Updates the acceptance tests and measurements for copper conductor telecommunications plant; includes a section on acceptance tests and measurements for fiber optic cable plant; includes a section on acceptance tests and measurements for voiceband data transmission; and includes a shield or armor ground resistance test to determine outer jacket cable damage.

DATES: Effective date: June 2, 1997.

Incorporation by reference: Incorporation by reference of certain publications listed in this final rule is approved by the Director of the Federal Register as of June 2, 1997.

FOR FURTHER INFORMATION CONTACT: Charlie I. Harper, Jr., Chief, Outside Plant Branch, Telecommunications Standards Division, Rural Utilities Service, room 2837, STOP 1598, South Building, U.S. Department of Agriculture, Washington, DC 20250–1598, telephone number (202) 720–0667.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This final rule has been determined to be not significant and therefore has not been reviewed by the Office of Management and Budget.

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. RUS has determined that this final rule meets the applicable standards provided in section 3 of that Executive Order.

Regulatory Flexibility Act Certification

The Administrator of RUS has determined that this final rule will not have a significant economic impact on a substantial number of small entities, as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This final rule involves standards and specifications, which may increase the direct short-term costs to RUS borrowers. However, the long-term direct economic costs are reduced through greater durability and lower maintenance cost over time.

Information Collection and Recordkeeping Requirements

The reporting and recordkeeping requirements contained in the final rule were approved by the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended) under control number 0572–0059.

Send questions or comments regarding this burden or any aspect of these collections of information, including suggestions for reducing the burden, to F. Lamont Heppe, Jr., Director, Program Support and Regulatory Analysis, Rural Utilities Service, U.S. Department of Agriculture,