

This statement is intended to clarify the policy of Biotechnology Regulatory Services (BRS), Animal and Plant Health Inspection Service (APHIS) regarding the authorization of environmental releases of certain genetically engineered organisms when the release is intended to last for more than one year. Field trials of any species that are intended to last more than one year, including perennials, biennials, and annuals left in the ground for more than 365 days, may be affected by this clarification.

Based upon accumulated regulatory experience and currently available science, APHIS is discontinuing the practice of acknowledging notifications for all environmental releases lasting longer than one year. Our experience shows that multiyear field tests can pose special challenges with respect to meeting the performance standards for notifications. In such cases, field test protocols are best tailored to the specific field test, with APHIS review and input, as is done under the permitting process. Thus, in order to provide the enhanced administrative oversight that is needed, all releases intended to last more than one year, including releases of perennials, biennials, and annuals left in the ground for more than 365 days, may only be authorized by permit, and not by notification.

This means that all field tests under acknowledged notifications **must be terminated within one year** from the date of the introduction, or before the expiration date of the acknowledged notification, whichever comes first. Further, “renewals” by means of a notification to extend the duration of the release period authorized by a prior acknowledged notification **will no longer be acknowledged**. Perennial and biennial species may still be grown under an acknowledged notification, so long as that release is fully terminated no later than one year from the date of introduction. All other releases of perennial and biennial species must be authorized under a permit and not under a notification.

Responsible parties who currently hold an acknowledged notification having a duration of more than one year must reapply for authorization under permit. APHIS will terminate all such multi-year notifications on September 10, 2008. If such releases are to continue beyond that date, responsible parties must apply for a permit **no less than six months prior** to the current expiration of the acknowledged notification or September 10, 2008, whichever comes first. Similarly, responsible parties originally intending to extend the authorization period of a release by “renewing” a notification by means of a notification can no longer do so. Rather, they must instead apply for a permit.

For those current releases of perennials or biennials authorized under notifications that will expire before March 10, 2008, if the responsible party wishes to continue the introduction beyond the termination date, APHIS may authorize the continued release under a new, non-renewable notification solely for the purpose of allowing the responsible party sufficient time to acquire a valid permit. For responsible parties who intended to release perennials or biennials under notification before March 10, 2008, and who have not yet submitted a notification, APHIS may similarly authorize the release under a non-renewable notification to allow sufficient time to acquire a valid permit.

If you are not already submitting applications via ePermits, we strongly encourage you to do so. This will greatly facilitate the review and approval process. You can learn more about ePermits at: [http://www.aphis.usda.gov/permits/learn\\_epermits.shtml](http://www.aphis.usda.gov/permits/learn_epermits.shtml)

If you have questions about this procedural change, please email [biotechquery@aphis.usda.gov](mailto:biotechquery@aphis.usda.gov).