

Overview of Improvements to Supplemental Permit Conditions

7 CFR 340.4(f) provides for supplemental permit conditions to be added to permits for imports, interstate movements, and releases of genetically engineered organisms regulated by APHIS. This document provides information to stakeholders regarding anticipated updates to supplemental permit conditions. This document is provided for informational purposes only and does not institute permit requirements. Permit requirements are specified in 7 CFR part 340 and in individual permits on a case by case basis.

Starting June 30, 2018, updates to supplemental permit conditions include:

General updates
Supplemental permit conditions that repeat the regulations (7 CFR 340) or that are guidance will be deleted, including: <ul style="list-style-type: none">• Language stating permittee’s legal responsibility to obtain all necessary Federal and State approvals• Language stating consultation with FDA may be required• Language in 7 CFR 340.4 that APHIS be provided access to records.
To increase consistency and clarity, language will be standardized across permits and ambiguous terms will be replaced, such as: <ul style="list-style-type: none">• Changing “not physically isolated” to “not separated sufficiently to prevent transmission” (movement of microbes with inoculation).
To increase consistency, clarity, and shared understanding among permittees, cooperators, and inspectors, APHIS will incorporate design protocols/SOPs provided by the applicant into the permit conditions by reference and will indicate that the permit conditions supersede the design protocols/SOPs in cases where there are differences.
Will include language that makes clear that a regulated article remains a regulated article even upon expiration of the permit, and must continue to be treated as a regulated article until it has been devitalized or APHIS has determined that it is not a regulated article.
Consistent with 7 CFR part 340.4(c), conditions will require approval from APHIS prior to within-state movement of regulated articles to any locations/destinations not authorized in the issued permit. This applies regardless of whether such movement occurs before or after the permit expires, unless the regulated article has been devitalized or APHIS has determined that the article is not a regulated article.

In order to ensure inspectors can *gain* access to locations where regulated articles are located, APHIS will state that trial sites must be maintained so as to allow access for inspectors through the end of the volunteer monitoring period and similarly, facilities and storage areas must be maintained so as to allow access for inspectors.

Updates to Microbe Movement Permits

In order to prevent dissemination and establishment of regulated articles, in accordance with 7 CFR 340.4(f)(1), supplemental permit conditions will include language stating that:

- Autoclaves used for devitalization must be calibrated by and have a valid certification from an authorized autoclave service company
- Plants inoculated with a regulated article must be treated as regulated articles.

Updates to Release Permits

The current condition that harvested plant material may not be used for food or feed unless first devitalized and approved for such use by the FDA and the EPA will be replaced with a condition that if propagatable regulated plant material is used for food or animal feed then all such food, feed and resulting waste must be treated as regulated material.

Regarding confinement requirements:

- Border rows must fall within the authorized field trial area and be treated as part of the field trial. Any plants growing in the border row must be treated as regulated articles and must be managed to allow for volunteer monitoring.

- If a perimeter zone (an area for maneuvering/movement of agricultural equipment) is used:
 - The perimeter zone must fall within the authorized field trial area, be treated as part of the field trial, and start outside any border rows. Perimeter zones may be fallow or planted to a morphologically distinct cover crop
 - Plants growing in the perimeter zone of field trial must be treated as regulated articles and managed to allow for volunteer monitoring
 - Perimeter zone must be at least 10 feet and must be wide enough to allow equipment to turn around.

Regarding volunteer monitoring requirements, updates include changes to improve consistency, clarity, and permittee/cooperator understanding of requirements. The conditions will indicate that:

- The areas planted, as well as areas where viable material is disposed, border rows, and perimeter zone must be monitored.
- The start date of the volunteer monitoring period for each field test site begins with the harvest/termination
- During the volunteer monitoring period, volunteer monitoring must occur whenever environmental conditions are conducive to plant growth

- If volunteers are found during the final monitoring intervals, volunteer monitoring must continue until no volunteers are found for 2 consecutive monitoring intervals during times when environmental conditions are conducive to plant growth (interval defined in permit)
- For plant backs (releases of regulated articles of the same species under a new or renewed authorization) volunteer monitoring must be done until the planting under the new authorization occurs. Once the planting under the new authorization occurs, the volunteer monitoring period for the plant-back area will be based on the new authorization.

Regarding equipment cleaning, conditions will:

- Indicate that cleaning of field, transport, and processing equipment must occur in an authorized area (where volunteer monitoring is required or on concrete/impermeable surface)
- Indicate that field equipment must be cleaned free of viable regulated material prior to being moved to any non-regulated site
- Allow for field equipment that has been partial cleaned in the field to be moved to a non-adjacent site if the equipment has been cleaned free of material that could dislodge during the movement
- Require that viable material removed from equipment during cleaning must be appropriately disposed of.

Starting January 1, 2019, updates to permit conditions may include the following:

Updates to Recordkeeping Requirements

(All permits): Requires maintenance of records sufficient to demonstrate compliance with the procedures, processes, and safeguards used to prevent escape, dissemination, and persistence of the regulated article, as specified in the current permit and permit conditions and any associated design protocols/SOPs; records must include who performed an activity and when.

(All permits): Records must be kept of the final disposition of the regulated article.

(Movement permits): Records must be kept of all points of origin and all intermediate and final locations/destinations of viable regulated material. Records must indicate the approximate amount and type of the regulated article, including strain or line identification, for each location.

(Release permits): Records of equipment cleaning must be kept, including who cleaned the equipment, when and where the cleaning was done, the methods of cleaning, and, if applicable, the methods and locations of disposal of viable material recovered from the equipment.

General Updates to Reporting Requirements

Regarding Unauthorized or Accidental Releases, the conditions will be revised as follows

- Examples of situations that require immediate verbal notification and written notification within 24 hours, will be included
- Permittees will be required to notify APHIS verbally and/or in writing within 5 days of any evidence of incursions of domestic (farm) animals.

To improve transparency, conditions for Planting Reports, Volunteer Monitoring Reports, and Field Test Reports will now include data fields that are already required or autopopulated in ePermits but that are not currently specified in the permit conditions.

Updates to Planting Reports

To facilitate effective compliance oversight and efficient and productive inspections, the permit conditions will require accurate information about field sites by specifying that

- If a location identified with a Planting Unique ID is replanted, a different Planting Unique ID must be provided for the new plantings
- GPS coordinates must be in decimal degrees and the release site must be described sufficiently to delineate the location and boundaries of the planting/release (e.g., providing multiple GPS coordinates, a map and/or written description of the site)
- A planting/release report of “no planting” or “no release” must be submitted no later than 30 calendar days after the expiration date of the permit, when no planting or release occurred for sites listed in the permit.

For plant-back situations where the volunteer monitoring period is still in effect for the original field trial, APHIS will require that the planting report for the plant-back field trial include the previous authorization number, location unique IDs, and planting unique IDs; this will enable APHIS to eliminate the volunteer monitoring requirement for plant-backs until the plant-back trial is terminated.

Updates to Volunteer Monitoring Reports

The requirement for annual monitoring reports prior to termination of a multi-year permit will be applied on a case-by-case basis rather than to all multi-year permits.

To facilitate effective compliance oversight and efficient and productive inspections, the permit conditions will require accurate information about volunteers by specifying that:

- The report must indicate the specific volunteer monitoring approach followed if multiple options were authorized, including the monitoring period, interval, and volunteer management requirements for the approach followed.
- All observations of volunteers must be reported
- For reporting the number of volunteers, a sampling strategy can be used if more than 100 volunteers identified
- The reports must include the developmental stage of any volunteers observed

- Annual post-termination volunteer monitoring reports will be required within specified times if volunteer monitoring extends for greater than one year
- When volunteer monitoring is not necessary (e.g., due to plant-back), a volunteer monitoring report is still required, but the report must specify “no monitoring” and include an explanation as to why monitoring did not occur and the new authorization number.

Updates to Field Test Reports – Annual and Final

With regards to field test reports: Under 7 CFR 340.4(f)(9), a field test report is required within 6 months after the termination of the field test

- We are deferring this requirement to no later than six months after the expiration date of the permit
- When a release occurs, we are indicating that the Field Test report is required, even if the permit is renewed or BRS authorizes all or part of any field test sites to be planted back.

The requirement for annual Field Test reports prior to termination of a multi-year permit will be applied on a case-by-case basis rather than to all multi-year permits.

To facilitate effective compliance oversight and efficient and productive inspections, the permit conditions will require accurate information about field tests by specifying that the Field Test report must include information about:

- Plant stage at time of termination
- For disposal, adds location, type and approximate amount of material disposed of
- For destruction/devitalization, adds the date, acreage, location, type of material devitalized, and method of devitalization
- If regulated material still growing in the field, it must be authorized by APHIS and the authorization number must be provided.

For stored material, allows permittees to report the *approximate* amount of material stored and includes the address and/or GPS coordinates in the requirement for description of location.