Guidance for Submission of Planting/Environmental Release Reports and Reports of No Planting /Release Submitted Via Email or Mail

Process for Planting Reports/ Release Reports and Reports of No Planting/Release Submitted Via Email or Mail

Planting (for plants)/release (for microbes and insects) reports or reports of no planting/release submitted via email or mail will be entered by Animal and Plant Health Inspection Service, Biotechnology Regulatory Services (APHIS BRS) staff into ePermits on behalf of the regulated entity. This process will ensure planting/release information in reports submitted via mail or email is readily available and identified by APHIS. This process improvement will enhance BRS' oversight of regulated field trials; it also supports recommendations in USDA Office of Inspector General Controls Over APHIS' Introduction of Genetically Engineered Organisms Audit Report 50601-0001-32.

Submission of Planting or Other Environmental Release Information

APHIS strongly encourages the submission of all reports and notices via ePermits using the link under "My Reports and Notices."

A link to instructions for submitting via ePermits is located here:

BRS Reports and Notices User Guide.pdf

However, other options are to submit reports and notices via email or paper. If submitting using these other methods, both CBI and CBI-deleted or non-CBI copies should be submitted via:

BRS E-mail:

BRSCompliance@aphis.usda.gov

OR

BRS Mail:

Animal and Plant Health Inspection Service (APHIS) Biotechnology Regulatory Services (BRS) Regulatory Operations Program 4700 River Rd. Unit 91 Riverdale, MD 20737

Note: This is general guidance, and required information that must be reported may vary based on the specific field trial or associated Supplemental Permit Conditions. Please contact BRS via email (BRSCompliance@aphis.usda.gov) or phone (BRS Compliance: 301-851-3879) for assistance and guidance.

Due Date of Report

All required planting/release information must be provided in a report,

The information contained in this document is intended as guidance, and reflects APHIS' current interpretation of applicable statutes and regulations. Except where noted, persons may choose to follow APHIS guidance or follow different procedures, practices, or protocols that meet applicable statutes and regulations. Language implying that guidance is mandatory (e.g., "shall," "must," "required," or "requirement") should not be construed as binding unless the terms are used to refer to a statutory or regulatory requirement.

Conversely, following the guidelines contained in this document should not be construed as a guarantee of compliance with applicable statutes and regulations. This guidance is to be used in conjunction with the USDA-APHIS BRS User's Guide for Notification and Permit's User's Guide.

preferably as an electronic file, no later than the 15th day of the month, or postmarked by the 15th day of the month, following the month in which the planting /release occurred (planting/release start date). When multiple plantings/releases are made under a single notification or permit (notifications and permits are collectively referred to as "authorizations"), a planting/release report must be submitted for each planting/release. However, the authorization holder may submit one or multiple reports, depending on factors that are meaningful, convenient, or important to their processes. If the plantings/releases occur with more than 30 days in between, these should appear on separate planting/release reports; however, for reporting purposes, authorization holders may define separate plantings/releases that occur at intervals shorter than 30 days.

For example, if two plantings/releases are made during the month of May, the planting/release information may be submitted in either one or two reports no later than June 15th. If a planting/release occurs in May and again in July, the first report must be submitted no later than June 15th and the second report must be submitted no later than August 15th.

Information to be Provided

In general, the information needed to satisfy the planting/release report requirements in a planting/release report should be arranged in a tabular, spreadsheet format. The information described below are consistent with the ePermits module that allows the web form entry or XML uploading of planting/release information into the system. For planting/release reports, the same information should be provided. An example planting report follows:



- **1. Authorization Number.** Report the notification or permit number.
- **2. Institution.** Report the institution name.
- **3. Article.** Report the regulated article.
- **4. State.** Report the name of the State in which the planting/release occurs.
- **5. County.** Depending on the State or territory, report the name of the County, parish, borough or municipality in which the planting/release occurs.
- **6.** Location Name. Report the authorized release site's Location name (farm level) the same as it is listed in the authorization. *Location Name is that used to designate the location, such as "Green's Farm."
- 7. Location Unique ID. This is an alphanumeric code that more specifically identifies the release site of the authorized planting/release and is used, among other reasons, to link all reports for the same authorized release location. It can be any combination of letters or

numbers that you choose, but it must be unique for each authorized release site within each authorization. If a Unique ID was provided for this authorized release site in the authorization, the applicant must use the same Unique ID in the planting/release report.

- **8. Report Date**. Report the date of report submission.
- **9. Planting/Release occurred.** Indicate whether or not a planting/release has occurred at this authorized release site. There are three possible entries: Use a "Y" if a planting/release occurred or an "N" if the release site will never be planted/released under this authorization. Leave the entry blank if no planting/release was made but the site will be, or may be, planted/released later under this authorization.

Note: All authorized release sites must be accounted for by submitting additional reports as necessary. See "Report Sites Not to be Planted/Released," below for sites that are never planted.

- **10. Planting/Release Unique ID.** For this authorization and individual release site, use a unique alphanumeric term or code to identify this unique planting/release at a specific field, plot or time. Use a simple planting/release identifier even if there will be only one planting/release at the unique site. Provide this identifier only if you entered "Y" for "planting/release occurred" (#9 above).
- 11. Planting/Release start date. Report the beginning date on which the unique release site was planted/release occurred (planting/release start date). Provide this date only if you entered "Y" for "planting/release occurred" (#9 above).
- **12. Acres Planted.** Report the total size of the planting/release, including only the area planted/released with the regulated article(s). This quantity must be submitted in acres; use no more than three decimal places. APHIS prefers that border rows not be included in this figure, even though they usually are treated as regulated during the release. For complex field designs that involve plantings/releases under multiple authorizations at one field location, report the planting/release size separately for each authorization, excluding border rows. For microbes and insects report the largest area of release. Provide the planting/release size only if you entered "Y" for "planting/release occurred" (**#9** above).
- **13. CBI information**. Use a "Y" if the GPS coordinates within the planting report are CBI. If other information within the report is CBI, use brackets [] to designate CBI information within the report. If CBI is involved, please submit both a CBI and CBI-deleted version.
- **14. Latitude coordinate.** Report a latitude coordinate for the planting/release in degree decimal format sufficient to delineate the boundaries of the unique release site (e.g., a

field within a farm). Up to six decimal places can be provided. Provide this coordinate only if you entered "Y" for "planting/release occurred" (#9 above). Example: 39.123456.

15. Longitude coordinate. Report the corresponding longitude coordinate in degree decimal format sufficient to delineate the boundaries of the unique release site (e.g., a field within a farm). Up to six decimal places can be provided. Each value is reported as a negative number. Provide this coordinate only if you entered "Y" for "planting/release occurred" (#9 above). Example: -101.123456.

NOTE: Up to six latitude/longitude pairs may be provided to define the perimeter of each unique planting/release location. However, if you report only one pair of coordinates, the latitude and longitude coordinates must be for the northwest corner, or northwestern-most point, of the field or plot planted/released. Convert GPS coordinates from degrees, minutes and seconds into decimal degree format using a website such as http://boulter.com/gps/.

- **16.** Constructs. The applicant should provide the constructs involved with this planting/release. Note that the phenotypic designations must be provided in the final field test report even if they have been provided earlier in planting/release reports.
- **17. Lines/Events**. The applicant may provide the lines/event involved with this planting/release. Note that the phenotypic designations must be provided in the final field test report even if they have been provided earlier in planting/release reports.
- **18. Location contact information.** Provide the name and contact information for the person responsible for conducting the planting/release at this specific location. Provide this contact information only if you entered "Y" for "planting/release occurred" (#9 above).
- **19. Anticipated harvest/termination date.** Provide the date on which the regulated article(s) planted/release is expected to be harvested or to be terminated prior to harvest.
- **20. Planting Comments.** Provide as text any comments or miscellaneous information relating to the planting/release. Examples of such information include information that the applicant has provided in the past or desires to add to the ePermits record (e.g., total acres planted, including borders, cumulative acres planted, whether all or part of the unique release site planted under a previous authorization was planted back under this authorization, permit renewal information, number of insects released). Note that multiple comments and information may be provided for each planting/release.

Identify in planting/release reports any authorized release sites included in the authorization that will not be planted at all or that no release will take place. Do not identify sites as "not planted" if they will be, or are likely to be, planted/released later under the authorization.

Note: All authorized release sites must be accounted for. If no planting/release occurs at an authorized release site, identify these sites as soon as you know that they will not be planted or no release will occur, but no later than one month after the expiration date of the authorization.

For reports of no planting/release, provide the following information:

Applicant reports these fields for all Locations								Applicant reports this field if Location is not planted
BRS Authorization Number	INSTITUTION	ARTICLE	State	County	Location Name	Loc Unique ID	Report Date	No Planting Explanation

- 1. Authorization Number. Report the authorization number.
- **2. Institution.** Report the institution name.
- **3. Article.** Report the regulated article.
- **4. State.** Report the name of the State in which the planting/release will not occur.
- **5. County.** Depending on the State or territory, report the name of the County, parish, borough or municipality in which the planting/release will not occur.
- **6. Location Name.** Report the authorized release site's Location name (farm level) the same as it is listed in the authorization. *Location Name is that used to designate the location, such as "Green's Farm."
- 7. Location Unique ID. This is an alphanumeric code that more specifically identifies the release site of the authorized planting/release and is used, among other reasons, to link all reports for the same authorized release location. It can be any combination of letters or numbers that you choose, but it must be unique for each release site within each authorization. If a Unique ID was provided for this release site in the authorization, the applicant must use the same Unique ID in the report of no planting/release.
- **8. Report Date**. Report the date of submission.
- **9. No Planting Explanation**. Provide as text any comments or miscellaneous information relating to the report of no planting/release.